

EPA REGISTRATION NUMBER 90335-1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 8, 2019

Dr. Priya Balachandran
VP Product Development and Marketing
Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Subject: PRIA Label Amendment – Revised to Add Claims
Product Name: SilvaClean
EPA Registration Number: 90335-1
Application Date: 09/06/2018
Decision Number: 544121

Dear Dr. Balachandran:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

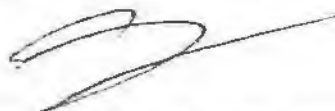
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Page 2 of 2
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Decision No. 544121

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Zeno Bain', with a long horizontal stroke extending to the right.

Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Approved label

Mar 08, 2019

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 90335-1

SilvaClean®

Laundry additive for residual activity against post-laundry contamination. Antimicrobial textile treatment for commercial and industrial use on fibers or textiles.

SilvaClean will kill 99.9% of *Staphylococcus aureus* after 6 hours of contact and 99.9% of *Klebsiella pneumoniae* after 3 hours of contact with SilvaClean treated fabric (cotton, cotton/polyester blend or microfiber materials).

SilvaClean® will kill 99.9% of *Candida albicans* after 6 hours of contact; 99.9% of, Vancomycin-resistant *Enterococcus faecalis* (VRE), *Acinetobacter baumannii*, and Extended-spectrum beta-lactamase (ESBL) positive *Escherichia coli* after 3 hours of contact; and Methicillin-Resistant *Staphylococcus aureus* (MRSA) after 9 hours of contact with SilvaClean®-treated fabric (cotton or cotton/polyester blend materials)

SilvaClean® will kill 99.9% of the following organisms on different types of textiles after the hours of contact time listed below:

Microorganism	Hours of Contact	Textile
<i>Staphylococcus aureus</i>	6 hours	Cotton, cotton/polyester blend, or microfiber
<i>Klebsiella pneumoniae</i>	3 hours	
Vancomycin-resistant <i>Enterococcus faecalis</i> (VRE)	3 hours	Cotton or cotton/polyester blend
Extended-spectrum beta-lactamase (ESBL) positive	3 hours	
<i>Acinetobacter baumannii</i>	3 hours	
<i>Candida albicans</i> (yeast)	6 hours	
Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	9 hours	

SilvaClean® also is effective in inhibiting the growth of stain- and odor-causing bacteria and fungi (mold and mildew) in products to which it is applied.

{These claims may appear on any label panel}

SilvaClean® is composed of:

Active Ingredient:

Silver*.....22.5%
Other Ingredients.....77.5%
Total.....100.0%

* from silver nitrate.

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive

See back panel for first aid and additional precautionary statements.

Net Contents: _____

EPA Reg. No. 90335-1

EPA Est. No. xxx-xx-x

Applied Silver, Inc.
 26254 Eden Landing Road
 Hayward, CA 94545

SilvaClean® is applied to or incorporated into industrial products listed below. For non-food contact uses only.

FOR COMMERCIAL AND INDUSTRIAL USE ONLY. Not for Residential Use.

Laundry additive with residual activity against *S. aureus* after 6 hours of contact and *K. pneumoniae* after 3 hours of contact on textiles made of cotton, cotton/polyester blend or microfiber materials. Examples include: pillow covers, sheets, blankets, bedspreads, apparel, uniforms, gowns, mops, cloths, and towels.

Laundry additive with residual activity against *C. albicans* after 6 hours of contact; Vancomycin-resistant *Enterococcus faecalis*, Extended-spectrum beta-lactamase positive *E. coli*, and *A. baumannii* after 3 hours of contact; and Methicillin-Resistant *S. aureus* after 9 hours of contact on textiles made of cotton or cotton/polyester blend. Examples include: pillow covers, sheets, blankets, bedspreads, apparel, uniforms, gowns, mops, cloths, and towels.

For material preservation against stain- and odor- causing bacteria and fungi (mold and mildew) of textiles made of: cotton or cotton/polyester blend, polyester, nylon, microfiber, spandex, and nylon/spandex blend. Example items include: pillow covers, sheets, blankets, bedspreads, apparel, uniforms, jerseys, active wear, scrubs, lab coats, quilts, liners, curtains, draperies, upholstery, towels, shower curtains, and carpets.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its label.

Laundry additive to reduce post-laundry contamination with residual activity against *S. aureus* (ATCC 6538) after 6 hours of contact and *K. pneumoniae* (ATCC 4352) after 3 hours of contact on textiles made of cotton, cotton/polyester blend or microfiber materials.

Laundry additive to reduce post-laundry contamination with residual activity against *C. albicans* (ATCC 10231) after 6 hours of contact; Vancomycin-resistant *E. faecalis*, (ATCC 51299) Extended-spectrum beta-lactamase positive *E. coli* (ATCC BAA-196), and *A. baumannii* (ATCC 19606), after 3 hours of contact; and Methicillin-Resistant *S. aureus* (ATCC 33591) after 9 hours of contact on cotton or cotton/polyester blend fabrics .

Laundry additive for preservation against stain- and odor-causing bacteria and fungi (mold and mildew).

Use as directed.

SilvaClean® is a concentrate that must be diluted with distilled or deionized water before use.

Following laundering and treatment with SilvaClean®, store clean, unused linens consistently with the facility's infection control practices. When linens are being used, SilvaClean® remaining in linens will reduce levels of *S. aureus* and *C. albicans* by 99.9% after 6 hours of contact; *K. pneumoniae*, Vancomycin-resistant *Enterococcus faecalis*, Extended-spectrum beta-lactamase positive *E. coli*, and *A. baumannii* by 99.9% after 3 hours of contact; and Methicillin-Resistant *S. aureus* by 99.9% after 9 hours of contact.

Dilute the following volumes of SilvaClean® concentrate volumes per 100 lbs of selected fabric type into 500 or 1000 mL distilled or deionized water and dose as part of the final rinse step in the laundry process to achieve residual post-laundry contamination reduction:

- 0.024 oz per 100 lbs cotton
- 0.032 oz per 100 lbs cotton/poly blend
- 0.048 oz per 100 lbs microfiber

Add the diluted solution into the final rinse cycle of a laundry process. Allow to soak with fabric at least 2 minutes.

Preservation against stain- and odor- causing bacteria and fungi (mold and mildew): Dilute SilvaClean® to provide 0.00016% to 0.0014% (1.6 ppm – 14 ppm) silver on fibers or textiles. The treatment level of SilvaClean® for a product will depend on the specific needs of the manufacturer, the textile being treated, and the level and type of performance desired.

Treat textile by soaking in dilute aqueous solution and agitating for at least 2 minutes.

Textile must be clean prior to the application of product. Retreat textile after each laundering.

Store and manage clean linens consistently with the facility's infection control program and best practices.

STORAGE and DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in a safe manner only in areas inaccessible to small children. Store in original container in dark location. Keep container tightly closed when not in use.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, intermediate mixtures, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA regional office for guidance.

Container Handling: RETURN THE CONTAINER TO APPLIED SILVER, INC. in the original outer packaging for appropriate disposal. Do not clean out, refill or dispose of this container.

PRECAUTIONARY STATEMENTS AND FIRST AID

DANGER

Corrosive

Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid breathing spray or mist. Wear goggles, face shield or safety glasses. Wear chemical-resistant apron over coveralls with long-sleeved shirt and long pants, waterproof gloves covering hands, wrists and lower forearms. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse.

First Aid

If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice.
If on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for treatment advice.
If swallowed:	Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a Poison Control Center or doctor for treatment advice.

For emergency information on SilvaClean®, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the Poison Control Center 1-800-222-1222.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters. This product is toxic to fish and aquatic invertebrates.

Optional Marketing Claims

Healthcare: As part of a diligent infection control program, experts recommend that a hospital should seek to reduce or eliminate exposure to pathogens to the greatest extent practical. One practical, inexpensive way to aid in this effort is to use SilvaClean® laundry additive. SilvaClean® provides residual post-laundry activity against the following pathogenic bacteria and yeast on cotton or cotton/polyester blend textiles: *S. aureus*, *C. albicans*, *K. pneumoniae*, VRE, ESBL *E. coli*, *A. baumannii* and MRSA. SilvaClean® provides residual post-laundry activity against the following pathogenic bacteria and yeast on microfiber textiles: *S. aureus* and *K. pneumoniae*. SilvaClean® has residual post-laundry activity against *S. aureus* and *C. albicans* after 6 hours of contact; *K. pneumoniae*, VRE, ESBL *E. coli*, and *A. baumannii* after 3 hours of contact; and MRSA after 9 hours of contact when textiles such as bed linens and patient gowns are laundered through the SilvaClean® program and properly stored. SilvaClean® may be a helpful addition to an Infection Control program. SilvaClean® is not a substitute for any existing component of a diligent Infection Control program. Practitioners should continue to implement fully all infection control measures.

Sports: As part of a diligent sports medicine Infection Control program, experts recommend that athletic programs should seek to reduce or eliminate exposure to pathogens to the greatest extent practical. One practical, inexpensive way to aid in this effort is to use SilvaClean® laundry additive. SilvaClean® provides residual post-laundry activity against the following pathogenic bacteria and yeast on cotton or cotton/polyester textiles: *S. aureus*, *C. albicans*, *K. pneumoniae*, VRE, ESBL *E. coli*, *A. baumannii* and MRSA.

SilvaClean® provides residual post-laundry activity against the following pathogenic bacteria and yeast on microfiber textiles: *S. aureus* and *K. pneumoniae*. SilvaClean® has residual post-laundry activity against *S. aureus* and *C. albicans* after 6 hours of contact; *K. pneumoniae*, VRE, ESBL *E. coli*, and *A. baumannii* after 3 hours of contact; and MRSA after 9 hours of contact when textiles such as uniforms, towels and practice apparel are laundered through the SilvaClean® program and properly stored. SilvaClean® may be a helpful addition to an Infection Control program. SilvaClean® is not a substitute for any existing component of a diligent Infection Control program. Practitioners should continue to implement fully all infection control measures.

Northern, Terria

From: Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Friday, March 08, 2019 1:55 PM
To: Bain, Zeno
Cc: Heather F. Collins, M.S.; Northern, Terria
Subject: RE: PRIA Completed Action 90335-1
Attachments: 00264498.pdf, 00264497.pdf

Importance: High

Zeno and Terria:

A redline version of the label showing this one additional change (document number 264498) and a clean version with the change accepted (document number 264497) are attached.

Please advise if you need us to do anything else.

Thank you and best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA ASIA | EUROPE | THE AMERICAS
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-266-5031 | F: 202-557-3836 | actagroup.com

From: Bain, Zeno <Bain.Zeno@epa.gov>
Sent: Friday, March 8, 2019 1:23 PM
To: Sheryl Lindros Dolan <sdolan@actagroup.com>
Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Northern, Terria <Northern.Terria@epa.gov>
Subject: RE: PRIA Completed Action 90335-1

Hi Sheryl

The option you provided, "inhibiting the growth of stain- and odor-causing bacteria and fungi (mold and mildew)", would be preferred. Would you be willing to make that adjustment? I recognize your initial language is on other labels but I think the option you provided is more clear.

Thank you

Zeno Bain
Product Manager 33

US Environmental Protection Agency
Antimicrobials Division (7510P)
Regulatory Management Branch I
2777 S. Crystal Drive
Arlington, VA 22202

ph. 703.347.8102

From: Sheryl Lindros Dolan <sdolan@actagroup.com>

Sent: Friday, March 08, 2019 11:51 AM

To: Bain, Zeno <Bain.Zeno@epa.gov>

Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Northern, Terria <Northern.Terria@epa.gov>

Subject: RE: PRIA Completed Action 90335-1

Zeno:

Let's speak, as the concern is not clear. We note again that mold and mildew are fungi, not bacteria, so suggesting that they are bacteria is objectionable.

We note the exact proposed language is used on other labels (e.g., see 84146-1).

We could say something like "inhibiting the growth of stain- and odor-causing bacteria and fungi (mold and mildew)", which is one variation that I have seen.

In the PR Notice, I would draw your attention to all the odor resistant claims in IV(B)(2).

I am available to discuss now if you wish.

Best regards,
Sheryl

SHERYL LINDROS DOLAN

SENIOR REGULATORY CONSULTANT

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From: Bain, Zeno <Bain.Zeno@epa.gov>

Sent: Friday, March 8, 2019 11:37 AM

To: Sheryl Lindros Dolan <sdolan@actagroup.com>

Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Northern, Terria <Northern.Terria@epa.gov>

Subject: RE: PRIA Completed Action 90335-1

Hi Sheryl

Can you point out specifically where it states "stain- and odor-causing bacteria, mold and mildew"? This was also something that the efficacy team preferred. It appears to be a list where mold and mildew are additional items to stain and odor causing bacteria. We would prefer it to be clear that the stain and odor causing bacteria area the mold and mildew bacteria.

Thank you

Zeno Bain

Product Manager 33

US Environmental Protection Agency

Antimicrobials Division (7510P)

Regulatory Management Branch I

2777 S. Crystal Drive

Arlington, VA 22202

ph. 703.347.8102

From: Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Thursday, March 07, 2019 3:32 PM
To: Bain, Zeno <Bain.Zeno@epa.gov>
Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Northern, Terria <Northern.Terria@epa.gov>
Subject: RE: PRIA Completed Action 90335-1

Zeno:

Applied Silver, Inc. (ASI) notes that mold and mildew are fungi, not bacteria, so they are uncomfortable making the change requested as it is not scientifically accurate.

We note stating "stain- and odor-causing bacteria, mold and mildew" seems consistent to us with the language in PR Notice 2000-1 for treated articles, which often is used as a basis for crafting non-public health antimicrobial claims. (That is, if EPA has stated that these claims can be made for treated articles, then presumably those claims can be made for the applied products.) For ease of reference, the link to PR Notice 2000-1 is <https://www.epa.gov/sites/production/files/2014-04/documents/pr2000-1.pdf>

If you agree, then please review the redline and clean labels that you currently have and we will not submit additional changes. If you disagree, please advise if we can speak.

Thank you,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

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From: Bain, Zeno <Bain.Zeno@epa.gov>
Sent: Thursday, March 7, 2019 2:16 PM
To: Sheryl Lindros Dolan <sdolan@actagroup.com>
Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Northern, Terria <Northern.Terria@epa.gov>
Subject: RE: PRIA Completed Action 90335-1

Hi Sheryl

Yes, please do.

Thank you

Zeno Bain
Product Manager 33

US Environmental Protection Agency
Antimicrobials Division (7510P)
Regulatory Management Branch I
2777 S. Crystal Drive
Arlington, VA 22202

ph. 703.347.8102

From: Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Thursday, March 07, 2019 2:15 PM
To: Bain, Zeno <Bain.Zeno@epa.gov>
Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Northern, Terria <Northern.Terria@epa.gov>
Subject: RE: PRIA Completed Action 90335-1

Thanks, Zeno.

We trust that you still want us to make the changes to the non-public health claims label that you specified - i.e., changing "Preservation against stain- and odor- causing bacteria, mold and mildew" to "Preservation against stain- and odor- causing mold and mildew bacteria". Given the timing, should we move that along and send those revisions to you?

Best,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

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From: Bain, Zeno <Bain.Zeno@epa.gov>
Sent: Thursday, March 7, 2019 2:11 PM
To: Sheryl Lindros Dolan <sdolan@actagroup.com>
Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Northern, Terria <Northern.Terria@epa.gov>
Subject: RE: PRIA Completed Action 90335-1

Hi Sheryl

I followed up with efficacy and they have corrected their response. They have verified that you have completed the testing for the original 2 organisms (*S. aureus* and *K. pneumoniae*) to support claims on microfiber. Therefore, the microfiber comments only refer to the new microbes. Do you have any additional edits to make on the label before I review again? I'll probably get to this tomorrow morning.

Thank you

Zeno Bain
Product Manager 33

US Environmental Protection Agency
Antimicrobials Division (7510P)
Regulatory Management Branch I
2777 S. Crystal Drive
Arlington, VA 22202

ph. 703.347.8102

From: Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Thursday, March 07, 2019 2:05 PM
To: Bain, Zeno <Bain.Zeno@epa.gov>
Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Northern, Terria <Northern.Terria@epa.gov>
Subject: RE: PRIA Completed Action 90335-1

Zeno,

Please confirm receipt of my subsequent e-mail

Thank you and best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

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From: Bain, Zeno <Bain.Zeno@epa.gov>
Sent: Thursday, March 7, 2019 1:17 PM
To: Sheryl Lindros Dolan <sdolan@actagroup.com>
Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Northern, Terria <Northern.Terria@epa.gov>
Subject: RE: PRIA Completed Action 90335-1

Hi Sheryl

Thank you for following up. I will look for a response tomorrow morning from you.

Thank you

Zeno Bain
Product Manager 33

US Environmental Protection Agency
Antimicrobials Division (7510P)
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From: Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Thursday, March 07, 2019 12:01 PM
To: Bain, Zeno <Bain.Zeno@epa.gov>
Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Northern, Terria <Northern.Terria@epa.gov>
Subject: RE: PRIA Completed Action 90335-1

Zeno:

We are reviewing and will circle back shortly. 1 p.m. today (1 hour from now) is unlikely as the client will need to sign off. We will do our utmost to send before 10 a.m. tomorrow to avoid the extension.

Thank you,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

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From: Bain, Zeno <Bain.Zeno@epa.gov>

Sent: Thursday, March 7, 2019 11:53 AM

To: Sheryl Lindros Dolan <sdolan@actagroup.com>

Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Northern, Terria <Northern.Terria@epa.gov>

Subject: RE: PRIA Completed Action 90335-1

Hi Sheryl

The claims against nylon and nylon blends (including microfiber) were not approved by the efficacy review (attached). At that time, we neglected to request that the claims be removed but we are requesting they be removed at this time since they are not supported by data.

Any non-public health claims should be clear as non-public health claims as well – for example, mold and mildew should be clear that it's stain or odor causing. I would prefer if you edit the title "Preservation against stain- and odor- causing bacteria, mold and mildew" to "Preservation against stain- and odor- causing mold and mildew bacteria". They currently appear to be additional items in the list versus the stain or odor causing bacteria that you are referring to.

Since the deadline is passed on this action, we need to complete it by today or tomorrow at the latest. If you send me the label by 1pm today, then I may be able to complete it today. If not, would you be able to send me a revised label by tomorrow morning 10am? If you are not able to send a revised label by tomorrow morning at 10am, accepting the comments from efficacy then I would request that we renegotiate the date on this action by ~60 days. If you are not able to send the revised label by tomorrow at 10am, please confirm your acceptance of the renegotiated PRIA deadline to 5/7/2019.

Thank you

Zeno Bain

Product Manager 33

US Environmental Protection Agency
Antimicrobials Division (7510P)
Regulatory Management Branch I
2777 S. Crystal Drive
Arlington, VA 22202

ph. 703.347.8102

From: Sheryl Lindros Dolan <sdolan@actagroup.com>

Sent: Thursday, March 07, 2019 9:53 AM

To: Northern, Terria <Northern.Terria@epa.gov>

Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>

Subject: RE: PRIA Completed Action 90335-1

Importance: High

Terria:

We suggest that we start with a review of the current, stamped label, accepted on April 25, 2018.

On the stamped label, microfiber claims are accepted, based on submitted data, for two microbes: *S. aureus* and *K. pneumoniae*.

On the stamped label there are also claims for a range of textiles for material preservation (i.e. non-public health claims).

In its December 20, 2018, memorandum, when the Efficacy Team states that claims should be removed for microfiber, we expect and understand that the Efficacy Team is referring to the new claims for the new microorganisms proposed for addition to the label as part of the pending label amendment. We do not expect nor believe that the Efficacy Team is looking back in time and rescinding previously approved claims.

New label claims are proposed for the following five microbes:

- Vancomycin-resistant *Enterococcus faecalis* (VRE)
- Extended-spectrum beta-lactamase (ESBL) positive
- *Acinetobacter baumannii*
- *Candida albicans* (yeast)
- Methicillin-Resistant *Staphylococcus aureus* (MRSA)

We have gone through the label and carefully revised it. As a result, hopefully it is clear that no claims are made for these new microbes for microfiber. We expect that the registrant will invest in the testing on microfiber for these microbes in the future and come back in to EPA to revise the label accordingly.

We note that the text for all the microbes is redline because we needed to move text around to make the distinction between what is approved already for microfiber and what will not be approved for microfiber as a result of this amendment application. Just because text is in redline, however, does not mean that it is "new" – it may be new text or it may be existing text that has been moved from where it appears on the current label. We so note in case this contributes to any confusion.

We hope this is clear. If it is not, we would be pleased to speak today to resolve any issues.

Thank you and best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

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From: Northern, Terria <Northern.Terria@epa.gov>

Sent: Wednesday, March 6, 2019 6:30 PM

To: Sheryl Lindros Dolan <sdolan@actagroup.com>

Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>

Subject: RE: PRIA Completed Action 90335-1

Hello Sheryl – I contacted you yesterday regarding removing the microfiber claim. You stated it a non-public health claim, allowed to remain on the label. Can you please provide clarification, we are on the verge of the label but the issue of the microfiber claims needs to be addressed.

Thanks!

Terria Northern

Registration Risk Manager
Environmental Protection Agency
1200 Penn. Ave., NW (7510P)

Washington, DC 20460
#703-347-0265 Office

Monday & Friday Telework 571-243-8932

Street address: 2777 Crystal Drive
1 Potomac Yard South
Arlington, VA

From: Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Friday, March 01, 2019 12:33 PM
To: Northern, Terria <Northern.Terria@epa.gov>
Cc: Heather F. Collins, M.S. <hcollins@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: PRIA Completed Action 90335-1

Terria:

Applied Silver, Inc. (ASI) is pleased to respond with the attached versions of the revised label for SilvaClean, U.S. Environmental Protection Agency (EPA) Reg. No. 90335-1. It is ASI's intent with this submission to implement exactly the label changes identified by EPA in its December 20, 2018, memorandum, received by ASI on February 19, 2019.

Attached are the following versions of the label:

- Document 263887 is a redlined comparison between the proposed label submitted in September 2018 for the pending application and the revised label submitted today; these redline changes highlight the changes made in response to EPA's recent comments.
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- Document 263761 is a clean version of the revised label submitted today, with all of EPA's comments implemented by ASI.

We hope this submission is clear and responsive. As always, please advise if there are any questions or comments.

Best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA ASIA | EUROPE | THE AMERICAS
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-266-5031 | F: 202-557-3836 | actagroup.com

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Friendly reminder we need the label by tomorrow COB.

Thanks!

Terria Northern

Registration Risk Manager
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Hello Sheryl – the Agency completed the final efficacy review, please see attachments. Contact me or Zeno if you have any questions or comments.

Thanks!



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: December 20, 2018

Subject: Efficacy Review for SilvaClean, EPA Reg. No. 90335-1
(DP Barcode: 449110, E-Submission: 32159)

From: Thao Pham
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P) *Thao Pham*

Thru: Kristen Willis, Team Leader
Product Science Branch
Antimicrobials Division (7510P) *Kristen Willis*
Date Signed: February 5, 2019

To: Zeno Bain, Team 33 / Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Silver	22.5%
<u>Other Ingredients</u>	77.5%
Total	100.0%

I BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment

Currently registered efficacy claim(s):

Requested action(s): Add supplemental residual self-sanitizing laundry additive claims.

Documents considered in this review:

- Letter from applicant to EPA dated September 6, 2018
- Data Matrix (EPA Form 8570-35), dated September 6, 2018
- 5 efficacy studies (MRID 50669002-50669006)
- Supplemental studies (MRID 50440501- 50440502)
- Revised Efficacy Review for DP 444670, dated April 17, 2018
- Proposed label dated 9/6/2018
- Confidential Statement of Formula (EPA Form 8670-4) dated 5/8/2014.

II PROPOSED DIRECTIONS FOR USE

"SilvaClean® is a concentrate that must be diluted with distilled or deionized water before use. Following laundering and treatment with SilvaClean®, store clean, unused linens consistently with the facility's infection control practices. When linens are being used, SilvaClean® remaining in linens will reduce levels of *S. aureus* and *C. albicans* by 99.9% after 6 hours of contact; *K. pneumoniae*, Vancomycin-resistant *Enterococcus faecalis*, Extended-spectrum beta-lactamase positive *E. coli*, and *A. baumannii* by 99.9% after 3 hours of contact; and Methicillin-Resistant *S. aureus* by 99.9% after 9 hours of contact.

Dilute the following volumes of SilvaClean® concentrate volumes per 100 lbs of selected fabric type into 500 or 1000 mL distilled or deionized water and dose as part of the final rinse step in the laundry process to achieve residual post-laundry contamination reduction:

- 0.024 oz per 100 lbs cotton
- 0.032 oz per 100 lbs cotton/poly blend
- 0.048 oz per 100 lbs microfiber

Add the diluted solution into the final rinse cycle of a laundry process. Allow to soak with fabric at least 2 minutes."

III STUDY SUMMARIES

1. MRID 504405-02 "Treating Fabric with Self-Sanitizing Laundry Test Solution" for Test Solution, by Sean Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1777.

This study was conducted to treat three fabric types, Microfiber (100% Polyester, lot: 286-E), Cotton (100%, lot: 286-A), and Cotton/Poly Blend (55% Cotton, 45% Polyester, lot: 286-B), with "Test Solution" (lots: 170821-1, 170821-2, and 170821-3) during laundry, according to Microchem Laboratory protocol P1937 (copy provided). The product, adjusted to the LCL concentration, was diluted to 0.0000310 ratio in 200ppm hard tap water for polyester, 0.0000155 for cotton, and 0.0000207 for blend. Product was applied during 23-minute rinse cycle with 2-minute soaking time; and 55-minute drying time.

Treated fabrics were assigned the following lot numbers:

- Treated Microfiber Fabric: M-1-11SEP2017A, M-2-11SEP2017A, and M-3-11SEP2017A
- Treated Cotton Fabric: C-1-12SEP2017A, C-2-12SEP2017A, and C-3-12SEP2017A
- Treated Cotton/Poly Blend Fabric: CP-1-12SEP2017A, CP-2-12SEP2017A, and CP-3-12SEP2017A

2. MRID 506690-02 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *E. coli* (ESBL)", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 23 Jul 2017. Laboratory Project Number GLP1861.

This study was conducted against *Escherichia coli* (ATCC BAA-196) (ESBL). Two lots (CP-1-12SEP2017A and CP-3-12SEP2017A) of Applied Silver's "Treated Cotton/Poly Blend Fabric", were tested according to Microchem Protocol P2050 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 23 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

Antibiotic resistance assay confirms ESBL positive profile.

3. MRID 506690-03 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *E. faecalis* (VRE)", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 23 Jul 2017. Laboratory Project Number GLP1865.

This study was conducted against *Enterococcus faecalis* (ATCC 51299) (VRE). Two lots (CP-1-12SEP2017A and CP-2-12SEP2017A) of Applied Silver's "Treated Cotton/Poly Blend Fabric", were tested according to Microchem Protocol P2053 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

Antibiotic resistance assay confirms organism is Vancomycin resistant.

4. MRID 506690-04 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *A. baumannii*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 23 Jul 2017. Laboratory Project Number GLP1853.

This study was conducted against *Acinetobacter baumannii* (ATCC 19606). Two lots (CP-1-12SEP2017A and CP-2-12SEP2017A) of Applied Silver's "Treated Cotton/Poly Blend Fabric", were tested according to Microchem Protocol P2047 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 23 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

5. MRID 506690-05 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *C. albicans*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 23 Jul 2017. Laboratory Project Number GLP1863.

This study was conducted against *Candida albicans* (ATCC 10231). Two lots (CP-1-12SEP2017A and CP-3-12SEP2017A) of Applied Silver's "Treated Cotton/Poly Blend Fabric", were tested according to Microchem Protocol P2048 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at 36±1°C for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 23 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes ± 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at 36±1°C.

6. MRID 506690-06 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *S. aureus* (MRSA)", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 24 Aug 2018. Laboratory Project Number GLP1966.

This study was conducted against *Staphylococcus aureus* (ATCC 33591) (MRSA). Two lots (CP-2-12SEP2017A and CP-3-12SEP2017A) of Applied Silver's "Treated Cotton/Poly Blend Fabric", were tested according to Microchem Protocol P2173 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at 36±1°C for 9 hours and 12 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes ± 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at 36±1°C.

Antibiotic resistance assay confirms organism is methicillin resistant.

IV STUDY RESULTS

Treated Cotton/Poly Blend Fabrics

MRID	Organism	Lot #	Time-Zero Control	% Reduction (Compared to Time-Zero)					
				30 min	1 hr	2 hr	3 hr	6 hr	24 hr
50669002	<i>Escherichia coli</i> (ATCC BAA-196) (ESBL)	CP-1-12SEP2017A	3.89 x 10 ⁵	0	8.74	92.06	99.9 90	>99.9 997	>99.9 997
		CP-3-12SEP2017A		0	14.91	97.91	99.9 94	99.99 898	99.99 91
50669003	<i>Enterococcus faecalis</i> (ATCC 51299) (VRE)	CP-1-12SEP2017A	3.09 x 10 ⁵	29.13	86.50	99.60	99.9 7	99.99 91	>99.9 997
		CP-2-12SEP2017A		29.13	80.94	99.76	99.9 86	99.99 91	>99.9 997
50669004	<i>Acinetobacter baumannii</i> (ATCC19606)	CP-1-12SEP2017A	2.82 x 10 ⁵	55.32	93.69	99.81	>99.9 996	>99.9 996	>99.9 996
		CP-2-12SEP2017A		22.34	92.77	99.56	99.9 5	>99.9 996	>99.9 996

50669005	<i>Candida albicans</i> (ATCC 10231)	CP-1- 12SEP2017A	1.66 x 10 ⁵	60.18	90.00	97.31	99.3 0	99.99 898	>99.9 994
		CP-3- 12SEP2017A		91.51	78.61	99.42	99.1 3	99.98 9	>99.9 994

MRID	Organism	Lot #	Time-Zero Control	% Reduction (Compared to Time-Zero Control)	
				9 hrs	12 hrs
50669006	<i>Staphylococcus aureus</i> (ATCC 33591) (MRSA)	CP-2- 12SEP2017A	1.48 x 10 ⁶	>99.99987	>99.99993
		CP-3- 12SEP2017A		>99.99991	>99.99993

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50669002 50669003 50669004	Post-laundry additive with residual activity	Laundered Dried Fabrics/ Textiles	Liquid, 0.0000207 for cotton/poly blend.	3 hours*	No soil load	200 ppm hard tap water	<ul style="list-style-type: none"> • <i>Escherichia coli</i> (ATCC BAA-196) (ESBL) • <i>Enterococcus faecalis</i> (ATCC 51299) (VRE) • <i>Acinetobacter baumannii</i> (ATCC19606) 	Yes
50669005	Post-laundry additive with residual activity	Laundered Dried Fabrics/ Textiles	Liquid, 0.0000207 for cotton/poly blend.	6 hours*	No soil load	200 ppm hard tap water	<ul style="list-style-type: none"> • <i>Candida albicans</i> (ATCC 10231) 	Yes
50669006	Post-laundry additive with residual activity	Laundered Dried Fabrics/ Textiles	Liquid, 0.0000207 for cotton/ poly blend.	9 hours*	No soil load	200 ppm hard tap water	<ul style="list-style-type: none"> • <i>Staphylococcus aureus</i> (ATCC 33591) (MRSA) 	Yes

* after 23-minute rinse cycle with 2-minute soaking time; and 55-minute drying time

VI LABEL COMMENTS

Label Date: 9/6/2018

1. Make the following changes to the proposed label:
 - a. Throughout the proposed label, remove claims against microfiber materials, nylon, and spandex. No testing was conducted to support nylon or nylon blend materials.
 - b. On page 1 of the proposed label,
 - i. revise "residual reduction of" to "residual activity against"
 - ii. further qualify "inhibiting the growth of bacteria, mold and mildew" to clearly distinguish this claim as a non-public health claim
 - c. On page 4 of the proposed label,
 - i. Remove or qualify "pathogenic bacteria and yeast" as this claim is too broad.

Northern, Terria

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Attachments: 00263887.pdf; 00263889.pdf; 00263761.pdf

Categories: Red Category

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

February 19, 2019

Sheryl L. Dolan
Senior Regulatory Consultant
2200 Penn. Ave. NW, Suite 100W
Washington, DC 20037

Subject: Pre-Decisional Determination
Product Name: SilvaClean
EPA Registration Number: 90335-1
Application Date: 09/06/2018
Decision Number: 544121

Dear Ms. Dolan:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified on the attached efficacy review dated December 20, 2018.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

- (a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
- (b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
- (c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Terria Northern at northern.terria@epa.gov or 703-347-0265.

Sincerely,

A handwritten signature in black ink, appearing to read "John Hebert" followed by a flourish.

John Hebert, Branch Chief
Regulatory Management Branch 1
Antimicrobials Division
Office of Pesticide Programs



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

November 7, 2018

Dr. Priya Balachandran
VP Product Development and Marketing
Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Subject: Technical Screen Failure
Product Name: SilvaClean
EPA Registration Number: 90335-1
Application Date: 10/24/2018
Decision Number: 545575

Dear Dr. Balachandran:

The U.S. Environmental Protection Agency (Agency or EPA) has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). The EPA has determined that your application has not passed the preliminary technical screening and therefore is subject to rejection if the application is not corrected.

- Please confirm that the substance identified as "Test Solution" in MRIDs 50559002-5066906 is the subject product. In addition, the Agency is requesting information regarding fabric treatment and test lot dilution. Unable to determine the product test concentration without this information

In order for the review of your pesticide product to continue, you will need to correct your application to address the items listed above within 10 business days of the date you received this letter. The EPA recommends sending your correction by email to the contact listed below to ensure it is received in a timely manner. If studies or confidential business information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application or do not respond within 10 business days, your application will be rejected. At this time, you could also choose to withdraw your application.

Page 2 of 2
EPA Reg. No. 90335-1
Decision No. 545575

If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Z. Bain', with a stylized flourish at the end.

for

Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Technical screen 90335-1

Technical Screen

EPA Reg#/File Symbol: 90335-1		E-Sub #: 32159	
DP Barcode: 449110		Submission #: 1024517	
Product name: SilvaClean		Registrant: Applied Silver, Inc.	
Reviewer's name: Thao Pham		Risk Manager: Zeno Bain / Terria Northern	
Completion due date: 11/6/18		Completion Date: 11/6/18	
Formulation type: Liquid <input checked="" type="checkbox"/> ; Towelettes <input type="checkbox"/> ; Spray <input type="checkbox"/> ; Solid <input type="checkbox"/> ; Textile <input type="checkbox"/> ; Aerosol <input type="checkbox"/> ; Other:			
Sterilant: <input type="checkbox"/>	Disinfectant: <input type="checkbox"/>	FC Sanitizer: <input type="checkbox"/>	NF Sanitizer <input type="checkbox"/> TB: <input type="checkbox"/> Fungicidal: <input type="checkbox"/> Virucide: <input type="checkbox"/>
MRID(s): 50669002, 50669003, 50669004, 50669005, 50669006			
PC Code(s)	Active Ingredient Names	% wt (label)	%LCL
072501	Silver	22.5	
Label Claims: Laundry additive residual self-sanitizer – Dilute concentrate 0.024, 0.032, or 0.048 oz with 100 lbs cotton, cotton/poly blend, or microfiber fabric, respectively, in 500 or 1000 mL distilled or deionized water in the final rinse cycle, allowing to soak at least 2 minutes.			
Product Lot(s)	Tested Concentration(s)	Tested at LCL	
170821-1	22.2, dilution unknown	Yes <input type="checkbox"/>	No <input type="checkbox"/>
170821-3	22.2, dilution unknown	Yes <input type="checkbox"/>	No <input type="checkbox"/>
170821-2	22.2, dilution unknown	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Tested: RTU <input type="checkbox"/> Diluted <input checked="" type="checkbox"/>		Tested Dilution Rate: unknown	
Certificate of Analysis: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		Performed by testing Lab: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
Test Lab: Microchem Laboratory			
Comments: Efficacy Review: Applicant is submitting data to support additional post laundry residual activity claims.			
Product is NOT cleared for technical screen:			
<ul style="list-style-type: none"> Please confirm that the substance identified as "Test Solution" in MRIDs 50559002-50669006 is the subject product. Please provide information regarding fabric treatment and test lot dilution. Unable to determine the product test concentration without this information. 			



November 20, 2018

Via CDX

Mr. Zeno Bain
Antimicrobials Division (7510P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard 7510P
2777 S. Crystal Drive
Arlington, VA 22202

Re: Response to Technical Screen Deficiency Letter, Decision Number 545575

Dear Mr. Bain:

In response to the U.S. Environmental Protection Agency's (EPA) November 7, 2018, letter relating to the pending amendment application for EPA Reg. No. 90335-1, Applied Silver, Inc. (ASI), and its consultant, The Acta Group (Acta[®]), corresponded with EPA by e-mail on November 9, 2018 (copy attached), to clarify the alleged technical screen deficiencies. Upon review, EPA stated that the information in the e-mail adequately addressed the issues in the technical screen letter and that the Antimicrobials Division is proceeding with review of this amendment application. ASI is providing this confirmatory letter within the 10-business-day response period to complete the record for EPA's files.

As discussed in the November 9, 2018, e-mail, ASI submitted a similar label amendment application on November 17, 2017, which EPA approved on April 25, 2018. As stated in the cover letter for the current submission: "ASI used laundered textile samples produced during the simulated use test previously reviewed by EPA for the efficacy testing to support the new claims proposed in this amendment application. The Master Record Identification (MRID) numbers for the simulated use testing information previously reviewed by EPA are included in the accompanying data matrix." The MRID for the volumes pertinent to the simulated use test (MRID Numbers 50440502 and 50504501) are cited in the data matrix for the current pending application. The information requested in EPA's November 7, 2018, letter is addressed in these volumes.

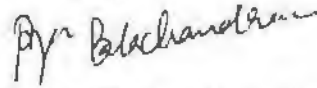
In addition, as stated in the attached e-mail, ASI confirms that the "Test Solution" in MRID Numbers 50559002-5066906 is the registered product subject to this amendment application.

{01433.001 / 111 / 00256248.DOCX 5}

Applied Silver Inc.
26254 Eden Landing Road
Hayward, CA 94545
888-939-4747

If there are any questions or comments about this submission, please contact Sheryl Lindros Dolan, The Acta Group, at (202) 266-5031 or sdolan@actagroup.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Priya Balachandran".

Priya Balachandran, Ph.D.
Vice President, Product Development and
Marketing
Applied Silver, Inc.

Attachment

Heather F. Collins, M.S.

From: Northern, Terria <Northern.Terria@epa.gov>
Sent: Tuesday, November 13, 2018 11:51 AM
To: Sheryl Lindros Dolan
Cc: Bain, Zeno; Heather F. Collins, M.S.
Subject: RE: EPA Request 90335-1

Hello Sheryl –

The MRIDs provided sufficiently address the tech screen.

Thanks!

Heather F. Collins
Registration Risk Manager
Environmental Protection Agency
1200 Penn. Ave., NW (7510P)
Washington, DC 20460
#703-347-0265 Office

Monday & Friday Telework 571-243-8932

Street address: 2777 Crystal Drive
1 Potomac Yard South
Arlington, VA

From: Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Friday, November 09, 2018 5:27 PM
To: Northern, Terria <Northern.Terria@epa.gov>
Cc: Bain, Zeno <Bain.Zeno@epa.gov>; Heather F. Collins, M.S. <hcollins@actagroup.com>
Subject: RE: EPA Request 90335-1
Importance: High

Zeno and Terria

We are confused by EPA's letter and request a call early next week so that we can provide EPA with a complete and timely response.

In the technical screen, the reviewer states, "Please provide information regarding fabric treatment and test lot dilution. Unable to determine the product test concentration without this information." We find this comment confusing for the following reason:

- Applied Silver Inc. (ASI) submitted a similar label amendment application on November 17, 2017, which EPA approved on April 25, 2018.
- As stated clearly in the cover letter for the current submission: "ASI used laundered textile samples produced during the simulated use test previously reviewed by EPA for the efficacy testing to support the new claims proposed in this amendment application. The Master Record Identification (MRID) numbers for the simulated use testing information previously reviewed by EPA are included in the accompanying data matrix."

ASI provided data sufficient for EPA to assess fabric treatment and test lot dilution for the amendment application approved on April 25, 2018. As stated in the cover letter for the pending application, the efficacy studies submitted to support the

current label amendment were conducted on fabric treated as part of the same simulated use test previously reviewed by EPA. EPA sought clarification regarding the fabric treatment and test lot dilution previously, to which ASI successfully responded. The MRID for the volumes pertinent to the simulated use test (MRID 50440502 and 50504501) are cited in the data matrix for the current pending application. As such, we are confused why the data concerning fabric treatment and test lot dilution that EPA found sufficient earlier this year are not now sufficient.

It appears to ASI that EPA already has the information that it has requested in the 10-day deficiency letter (apart from confirming that the efficacy studies submitted were conducted on fabric that was treated with the currently registered product, which ASI will be pleased to confirm). ASI requests a call, however, to confirm that we are not missing anything.

Thank you and best regards,
Sheryl Dolan

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA ASIA | EUROPE | THE AMERICAS
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20025
T: 202-266-6031 | F: 202-557-3836 | actagroup.com

From: Northern, Terria <Northern.Terria@epa.gov>
Sent: Wednesday, November 7, 2018 1:53 PM
To: Sheryl Lindros Dolan <sdolan@actagroup.com>
Cc: Bain, Zeno <Bain.Zeno@epa.gov>
Subject: EPA Request 90335-1

Hello Sheryl – the Agency completed the initial technical screen for the EPA registration number 90335-1 and the data failed. Please review and respond to the deficiencies listed in the attached letter within 10 business days. Questions or comments contact me directly or Zeno Bain.


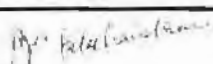
Thanks!

Teresa Henderson
Registration Risk Manager
Environmental Protection Agency
1200 Penn. Ave., NW (7510P)
Washington, DC 20460
#703-347-0265 Office

Monday & Friday Telework 571-243-8932

Street address: 2777 Crystal Drive
1 Potomac Yard South
Arlington, VA

<div style="display: inline-block; text-align: center; margin-left: 20px;"> United States Environmental Protection Agency Washington, DC 20460 </div>		Registration	OPP Identifier Number
		X Amendment	
		Other	
Application for Pesticide - Section I			
1. Company/Product Number 90335-1		2. EPA Product Manager Zeno Bain	
4. Company/Product (Name) SilvaClean®		3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include Zip Code) Applied Silver, Inc. 26254 Eden Landing Road Hayward, CA 94545 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Notification - Explain below. <input checked="" type="checkbox"/> Other - Explain below.			
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) In its November 9, 2018, to November 13, 2018, e-mail exchange with the Antimicrobials Division, Applied Silver Inc. (ASI) resolved the issues raised in AD's November 7, 2018, 10-day deficiency letter, Decision No. 545575. ASI is submitting the accompanying letter and copy of the e-mail exchange to complete EPA's files for the pending amendment application to add additional microorganisms and related claims to the label for SilvaClean®, EPA Reg. No. 90335-1.			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 and 2 liters	
		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Sheryl Lindros Dolan		Title Agent	Telephone No. (Include Area Code) (202) 266-5031
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <div style="border: 1px solid black; width: 100px; height: 100px; margin: 0 auto;"></div> (Stamped)
2. Signature 		3. Title VP Product Development and Marketing	
4. Typed Name Dr. Priya Balachandran		5. Date November 20, 2018	

 <div style="display: inline-block; text-align: center;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">Registration</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">X Amendment</div> <div style="border: 1px solid black; padding: 2px;">Other</div>	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 90335-1	2. EPA Product Manager Zeno Bain	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) SilvaClean®	PM# 33		
5. Name and Address of Applicant (Include Zip Code) Applied Silver, Inc. 26254 Eden Landing Road Hayward, CA 94545 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section - II			
<div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below. </div> <div> <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below. </div> </div>			
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) This application is an amendment to add additional microorganisms and related claims to the label for SilvaClean®, EPA Reg. No. 90335-1. Applied Silver expects that EPA will place this application into PRIA 3, Category A570, with a \$3,831 fee and 4-month review.			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1 and 2 liters	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Other _____ <input type="checkbox"/> Stenciled			
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Sheryl Lindros Dolan	Title Agent	Telephone No. (Include Area Code) (202) 266-5031	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <div style="text-align: center;">(Stamped)</div>
2. Signature 	3. Title VP Product Development and Marketing		
4. Typed Name Dr. Priya Balachandran	5. Date September 6, 2018		



September 6, 2018

Via CDX Electronic Submission

Mr. Zeno Bain
Document Processing Desk
U.S. Environmental Protection Agency
Office of Pesticide Programs
7504P, Room S-4900
One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Re: Application to Amend SilvaClean[®] Registration, EPA Reg. No. 90335-1

Dear Mr. Bain:

Applied Silver, Inc. (ASI) is pleased to submit to the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) Antimicrobials Division (AD) the accompanying application to amend SilvaClean[®], EPA Reg. No. 90335-1, which currently is registered as a "Laundry additive to reduce post-laundry contamination with residual activity against *Staphylococcus aureus* after 6 hours of contact and *Klebsiella pneumoniae* after 3 hours of contact. Antimicrobial textile treatment for commercial and industrial use on fibers or textiles. SilvaClean[®] is effective in inhibiting the growth of bacteria, mold and mildew in products to which it is applied. SilvaClean[®] will kill 99.9% of *S. aureus* after 6 hours of contact and 99.9% of *K. pneumoniae* after 3 hours of contact with SilvaClean[®] treated fabric (cotton, cotton/polyester blend and microfiber materials)".

As discussed during a pre-submission meeting between ASI and OPP on October 24, 2017, and during a subsequent meeting between ASI and OPP on April 12, 2018, ASI is submitting this application to extend the list of approved kill claims to include the following microorganisms:

- Vancomycin-resistant *Enterococcus faecalis* (VRE)
- Extended-spectrum beta-lactamase positive (ESBL) *Escherichia coli*
- *Acinetobacter baumannii*
- *Candida albicans* (yeast)
- Methicillin-Resistant *Staphylococcus aureus* (MRSA)

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Applied Silver Inc.
26254 Eden Landing Road
Hayward, CA 94545
888-939-4747

These microorganisms have been selected due to their prevalence as problematic post-laundry contaminants in healthcare and sports settings. The enclosed discussion volume (Volume 1) highlights healthcare laundry industry best practices and peer reviewed literature that outline the current challenges posed by these post-laundry contaminants.

ASI previously followed the Office of Chemical Safety and Pollution Prevention (OCSPP) Guideline 810.2400(e)(1), to generate the data submitted on November 17, 2017, in support of the registration amendment approved on April 25, 2018. As part of that testing, ASI relied on the simulated use test specified in the guideline to produce the laundered textile samples for the subsequent efficacy testing. SilvaClean laundry additive was used to treat the standard hospital linen made of 55%/45% cotton/polyester blend in a simulated use test, where it was added to fabric in the final step of a laundering process. ASI used laundered textile samples produced during the simulated use test previously reviewed by EPA for the efficacy testing to support the new claims proposed in this amendment application. The Master Record Identification (MRID) numbers for the simulated use testing information previously reviewed by EPA are included in the accompanying data matrix.

Consistent with the Guideline, efficacy testing was conducted on the treated fabric according to AATCC Method 100-2012 for the following microorganisms: Vancomycin-resistant *Enterococcus faecalis* (ATCC 51299), Extended-spectrum beta-lactamase positive *Escherichia coli* (ATCC BAA-196), *Acinetobacter baumannii* (ATCC 19606), *Staphylococcus aureus* (ATCC 33591), and *Candida albicans* (ATCC 10231). The results of the successful Good Laboratory Practice (GLP) efficacy testing are presented in the accompanying Volumes 2-6.

Accompanying this submission are the following supporting documents:

- Transmittal document;
- Pesticide Registration Improvement Extension Act (PRIA 3) fee payment receipt;
- Proposed label (redlined and clean versions);
- EPA Forms 8570-1, 8570-34, and 8570-35 (confidential and public versions);
- Volume 1: A discussion volume that reviews the efficacy testing and proposed claims, and includes copies of correspondence and related documentation exchanged with EPA pertinent to this amendment application.
- Volumes 2-6: efficacy studies, for the five microorganisms.

Mr. Zeno Bain
September 6, 2018
Page 3

ASI looks forward to working with the Antimicrobials Division to make this amendment to its product label. If there are any questions or comments about this submission, please contact Sheryl Lindros Dolan, The Acta Group, at (202) 266-5031 or sdolan@actagroup.com.

Sincerely,



Dr. Priya Balachandran
Vice President Product Development and Marketing
Applied Silver, Inc.

cc: Mr. John Hebert (letter only)

Transmittal DocumentName and Address of Submitter:

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Company No.: 90335
Contact Person: Dr. Priya Balachandran
Title: VP Product Development and Marketing
Telephone: 1 (888) 939 4747
E-Mail: priya@appliedsilver.com

Individual to be contacted, if necessary, to process this application:

The Acta Group, L.L.C.
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, D.C. 20037-1701

Contact Person: Sheryl Lindros Dolan
Telephone: (202) 266-5031
Fax: (202) 557-3836
E-Mail: sdolan@actagroup.com

Regulatory Actions: This application is an amendment to add additional microorganisms and related claims to the label for SilvaClean[®], EPA Reg. No. 90335-1. Applied Silver expects that EPA will place this application into PRIA 3, Category A570, with a fee of \$3,831.00 and a 4-month review period.

Transmittal Date: September 6, 2018

List of Submitted Studies:

Vol.	Contents	Guideline No.	Study Report Title	MRID No.
1	Amendment Overview and Discussion of Proposed Label Claims	810.2400	Background and Discussion for Proposed Label Claims, Report No.1433.001-03, September 5, 2018, 383 p.	50669001
2	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>E. coli</i> (ESBL), Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP1861, July 23, 2018, 49 p.	50669002

Vol.	Contents	Guideline No.	Study Report Title	MRID No.
3	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>E. faecalis</i> (VRE), Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP18653, July 23, 2018, 44 p.	50669003
4	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>A. baumannii</i> , Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP1853, July 23, 2018, 44 p.	50669004
5	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>C. albicans</i> , Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP1863, July 23, 2018, 44 p.	50669005
6	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>S. aureus</i> (MRSA), Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP1966, August 24, 2018, 39 p.	50669006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 12, 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-544121
EPA File Symbol or Registration Number: 90335-1
Product Name: SilvaClean
EPA Receipt Date: 06-Sep-2018
EPA Company Number: 90335
Company Name: APPLIED SILVER, INC.

SHERYL LINDROS DOLAN
THE ACTA GROUP
AGENT FOR APPLIED SILVER, INC.
2200 PENN. AVE., N.W., SUITE 100W
WASHINGTON, DC 20037-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A570

AMENDMENT;NON-FAST TRACK;REQUIRING DATA REVIEW;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8154.

Sincerely,

A handwritten signature in black ink, appearing to be "J. J. J.", written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division



Receipt

Your payment is complete

Pay.gov Tracking ID: 26C30GUH

Agency Tracking ID: 75567849458

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card

Payment Amount: \$3,831.00

Transaction Date: 09/06/2018 03:30:28 PM EDT

Payment Date: 09/06/2018

Registration Number: 90335-1

Company Name: Applied Silver

Company Number: 90335

Action Code: A570

Account Information

Cardholder Name: Juinan Wang

Card Type: Master Card

Card Number: *****4291

Email Confirmation Receipt

Confirmation Receipts have been emailed to:

joyce@appliedsilver.com



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C 20460

September 12, 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

APPLIED SILVER, INC.
26254 EDEN LANDING ROAD
HAYWARD, CA 94545

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 06-SEP-18. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Transmittal DocumentName and Address of Submitter:

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Company No.: 90335
Contact Person: Dr. Priya Balachandran
Title: VP Product Development and Marketing
Telephone: 1 (888) 939 4747
E-Mail: priya@appliedsilver.com

Individual to be contacted, if necessary, to process this application:

The Acta Group, L.L.C.
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, D.C. 20037-1701

Contact Person: Sheryl Lindros Dolan
Telephone: (202) 266-5031
Fax: (202) 557-3836
E-Mail: sdolan@actagroup.com

Regulatory Actions: This application is an amendment to add additional microorganisms and related claims to the label for SilvaClean[®], EPA Reg. No. 90335-1. Applied Silver expects that EPA will place this application into PRA 3, Category A570, with a fee of \$3,831.00 and a 4-month review period.

Transmittal Date: September 6, 2018

List of Submitted Studies:

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September 6, 2018

Via CDX Electronic Submission

Mr. Zeno Bain
Document Processing Desk
U.S. Environmental Protection Agency
Office of Pesticide Programs
7504P, Room S-4900
One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Re: Application to Amend SilvaClean[®] Registration, EPA Reg. No. 90335-1

Dear Mr. Bain:

Applied Silver, Inc. (ASI) is pleased to submit to the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) Antimicrobials Division (AD) the accompanying application to amend SilvaClean[®], EPA Reg. No. 90335-1, which currently is registered as a "Laundry additive to reduce post-laundry contamination with residual activity against *Staphylococcus aureus* after 6 hours of contact and *Klebsiella pneumoniae* after 3 hours of contact. Antimicrobial textile treatment for commercial and industrial use on fibers or textiles. SilvaClean[®] is effective in inhibiting the growth of bacteria, mold and mildew in products to which it is applied. SilvaClean[®] will kill 99.9% of *S. aureus* after 6 hours of contact and 99.9% of *K. pneumoniae* after 3 hours of contact with SilvaClean[®] treated fabric (cotton, cotton/polyester blend and microfiber materials)".

As discussed during a pre-submission meeting between ASI and OPP on October 24, 2017, and during a subsequent meeting between ASI and OPP on April 12, 2018, ASI is submitting this application to extend the list of approved kill claims to include the following microorganisms:

- Vancomycin-resistant *Enterococcus faecalis* (VRE)
- Extended-spectrum beta-lactamase positive (ESBL) *Escherichia coli*
- *Acinetobacter baumannii*
- *Candida albicans* (yeast)
- Methicillin-Resistant *Staphylococcus aureus* (MRSA)

{01433.001 / 111 / 00249308.DOCX 9}

Applied Silver Inc.
26254 Eden Landing Road
Hayward, CA 94545
888-939-4747

These microorganisms have been selected due to their prevalence as problematic post-laundry contaminants in healthcare and sports settings. The enclosed discussion volume (Volume 1) highlights healthcare laundry industry best practices and peer reviewed literature that outline the current challenges posed by these post-laundry contaminants.

ASI previously followed the Office of Chemical Safety and Pollution Prevention (OCSPP) Guideline 810.2400(e)(1), to generate the data submitted on November 17, 2017, in support of the registration amendment approved on April 25, 2018. As part of that testing, ASI relied on the simulated use test specified in the guideline to produce the laundered textile samples for the subsequent efficacy testing. SilvaClean laundry additive was used to treat the standard hospital linen made of 55%/45% cotton/polyester blend in a simulated use test, where it was added to fabric in the final step of a laundering process. ASI used laundered textile samples produced during the simulated use test previously reviewed by EPA for the efficacy testing to support the new claims proposed in this amendment application. The Master Record Identification (MRID) numbers for the simulated use testing information previously reviewed by EPA are included in the accompanying data matrix.

Consistent with the Guideline, efficacy testing was conducted on the treated fabric according to AATCC Method 100-2012 for the following microorganisms: Vancomycin-resistant *Enterococcus faecalis* (ATCC 51299), Extended-spectrum beta-lactamase positive *Escherichia coli* (ATCC BAA-196), *Acinetobacter baumannii* (ATCC 19606), *Staphylococcus aureus* (ATCC 33591), and *Candida albicans* (ATCC 10231). The results of the successful Good Laboratory Practice (GLP) efficacy testing are presented in the accompanying Volumes 2-6.

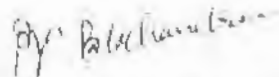
Accompanying this submission are the following supporting documents:

- Transmittal document;
- Pesticide Registration Improvement Extension Act (PRIA 3) fee payment receipt;
- Proposed label (redlined and clean versions);
- EPA Forms 8570-1, 8570-34, and 8570-35 (confidential and public versions);
- Volume 1: A discussion volume that reviews the efficacy testing and proposed claims, and includes copies of correspondence and related documentation exchanged with EPA pertinent to this amendment application.
- Volumes 2-6: efficacy studies, for the five microorganisms.

Mr. Zeno Bain
September 6, 2018
Page 3

ASI looks forward to working with the Antimicrobials Division to make this amendment to its product label. If there are any questions or comments about this submission, please contact Sheryl Lindros Dolan, The Acta Group, at (202) 266-5031 or sdolan@actagroup.com.

Sincerely,



Dr. Priya Balachandran
Vice President Product Development and Marketing
Applied Silver, Inc.

cc: Mr. John Hebert (letter only)

Transmittal Document

Name and Address of Submitter:

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Company No.: 90335
Contact Person: Dr. Priya Balachandran
Title: VP Product Development and Marketing
Telephone: 1 (888) 939 4747
E-Mail: priya@appliedsilver.com

Individual to be contacted, if necessary, to process this application:

The Acta Group, L.L.C.
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, D.C. 20037-1701

Contact Person: Sheryl Lindros Dolan
Telephone: (202) 266-5031
Fax: (202) 557-3836
E-Mail: sdolan@actagroup.com

Regulatory Actions: This application is an amendment to add additional microorganisms and related claims to the label for SilvaClean[®], EPA Reg. No. 90335-1. Applied Silver expects that EPA will place this application into PRIA 3, Category A570, with a fee of \$3,831.00 and a 4-month review period.

Transmittal Date: September 6, 2018

List of Submitted Studies:

Vol.	Contents	Guideline No.	Study Report Title	MRID No.
1	Amendment Overview and Discussion of Proposed Label Claims	810.2400	Background and Discussion for Proposed Label Claims, Report No.1433.001-03, September 5, 2018, 383 p.	50669001
2	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>E. coli</i> (ESBL), Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP1861, July 23, 2018, 49 p.	50669002

Vol.	Contents	Guideline No.	Study Report Title	MRID No.
3	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>E. faecalis</i> (VRE), Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP18653, July 23, 2018, 44 p.	50669003
4	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>A. baumannii</i> , Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP1853, July 23, 2018, 44 p.	50669004
5	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>C. albicans</i> , Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP1863, July 23, 2018, 44 p.	50669005
6	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>S. aureus</i> (MRSA), Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP1966, August 24, 2018, 39 p.	50669006



September 6, 2018

Via CDX Electronic Submission

Mr. Zeno Bain
Document Processing Desk
U.S. Environmental Protection Agency
Office of Pesticide Programs
7504P, Room S-4900
One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Re: Application to Amend SilvaClean[®] Registration, EPA Reg. No. 90335-1

Dear Mr. Bain:

Applied Silver, Inc. (ASI) is pleased to submit to the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) Antimicrobials Division (AD) the accompanying application to amend SilvaClean[®], EPA Reg. No. 90335-1, which currently is registered as a "Laundry additive to reduce post-laundry contamination with residual activity against *Staphylococcus aureus* after 6 hours of contact and *Klebsiella pneumoniae* after 3 hours of contact. Antimicrobial textile treatment for commercial and industrial use on fibers or textiles. SilvaClean[®] is effective in inhibiting the growth of bacteria, mold and mildew in products to which it is applied. SilvaClean[®] will kill 99.9% of *S. aureus* after 6 hours of contact and 99.9% of *K. pneumoniae* after 3 hours of contact with SilvaClean[®] treated fabric (cotton, cotton/polyester blend and microfiber materials)".

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- *Candida albicans* (yeast)
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{01433-001 / 111 / 00249308.DOCX 9}

Applied Silver Inc.
26254 Eden Landing Road
Hayward, CA 94545
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These microorganisms have been selected due to their prevalence as problematic post-laundry contaminants in healthcare and sports settings. The enclosed discussion volume (Volume 1) highlights healthcare laundry industry best practices and peer reviewed literature that outline the current challenges posed by these post-laundry contaminants.

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Consistent with the Guideline, efficacy testing was conducted on the treated fabric according to AATCC Method 100-2012 for the following microorganisms: Vancomycin-resistant *Enterococcus faecalis* (ATCC 51299), Extended-spectrum beta-lactamase positive *Escherichia coli* (ATCC BAA-196), *Acinetobacter baumannii* (ATCC 19606), *Staphylococcus aureus* (ATCC 33591), and *Candida albicans* (ATCC 10231). The results of the successful Good Laboratory Practice (GLP) efficacy testing are presented in the accompanying Volumes 2-6.

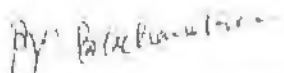
Accompanying this submission are the following supporting documents:

- Transmittal document;
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- Proposed label (redlined and clean versions);
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Mr. Zeno Bain
September 6, 2018
Page 3

ASI looks forward to working with the Antimicrobials Division to make this amendment to its product label. If there are any questions or comments about this submission, please contact Sheryl Lindros Dolan, The Acta Group, at (202) 266-5031 or sdolan@actagroup.com.

Sincerely,



Dr. Priya Balachandran
Vice President Product Development and Marketing
Applied Silver, Inc.

cc: Mr. John Hebert (letter only)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 25, 2018

Sheryl Lindros Dolan
Agent
Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Subject: PRIA Label Amendment – Adding Public Health Uses to the Product
Product Name: SilvaClean
EPA Registration Number: 90335-1
Application Date: 11/17/2017
Decision Number: 536139

Dear Ms. Dolan:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Page 2 of 2
EPA Reg. No. 90335-1
Decision No. 536139

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at heffernan.aline@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Zeno Bain', with a long horizontal stroke extending to the right.

Zeno Bain, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Stamped Label

SilvaClean®

Laundry additive to reduce post-laundry contamination with residual activity against *Staphylococcus aureus* after 6 hours of contact and *Klebsiella pneumoniae* after 3 hours of contact. Antimicrobial textile treatment for commercial and industrial use on fibers or textiles. SilvaClean® is effective in inhibiting the growth of bacteria, mold and mildew in products to which it is applied. SilvaClean will kill 99.9% of *S. aureus* after 6 hours of contact and 99.9% of *K. pneumoniae* after 3 hours of contact with SilvaClean-treated fabric (cotton, cotton/polyester blend and microfiber materials). {These claims may appear on any label panel}

SilvaClean® is composed of:

Active Ingredient:

Silver*22.5%
Other Ingredients.....77.5%
Total.....100.0%

* from silver nitrate.

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive

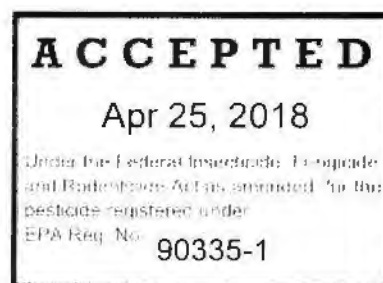
See back panel for first aid and additional precautionary statements.

Net Contents: _____

EPA Reg. No. 90335-1

EPA Est. No. xxx-xx-x

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545



SilvaClean® is applied to or incorporated into industrial products listed below. For non-food contact uses only.

FOR COMMERCIAL AND INDUSTRIAL USE ONLY. Not for Residential Use.

Laundry additive with residual activity against *S. aureus* after 6 hours of contact and *K. pneumoniae* after 3 hours of contact on textiles made of cotton, cotton/polyester blend, and microfiber. Examples include: pillow covers; sheets; blankets; bedspreads; apparel; uniforms, mops, cloths, towels.

For material preservation of textiles made of: cotton and cotton/polyester blend, polyester, nylon, microfiber, spandex, and nylon/spandex blend. Example items include: pillow covers; sheets; blankets; bedspreads; apparel; uniforms; jerseys; active wear; scrubs; lab coats; quilts; liners; curtains; draperies; upholstery; towels; shower curtains; and carpets.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its label.

Laundry additive to reduce post-laundry contamination with residual activity against *S. aureus* (ATCC 6538) after 6 hours of contact and *K. pneumoniae* (ATCC4352) after 3 hours of contact on cotton, cotton/polyester blends, and microfiber fabrics and for preservation against stain- and odor-causing bacteria, mold and mildew use as directed.

SilvaClean® is a concentrate that must be diluted with distilled or deionized water before use.

Following laundering and treatment with SilvaClean, store clean, unused linens consistently with the facility's infection control practices. When linens are being used, SilvaClean remaining in linens will reduce levels of *S. aureus* by 99.9 % after 6 hours of contact and *K. pneumoniae* by 99.9% after 3 hours of contact.

Dilute the following volumes of SilvaClean® concentrate volumes per 100 lbs of selected fabric type into 500 or 1000 mL distilled or deionized water and dose as part of the final rinse step in the laundry process to achieve residual post-laundry contamination reduction:

- 0.024 oz per 100 lbs cotton
- 0.032 oz per 100 lbs cotton/poly blend
- 0.048 oz per 100 lbs microfiber

Add the diluted solution into the final rinse cycle of a laundry process. Allow to soak with fabric at least 2 minutes.

Preservation against stain- and odor- causing bacteria, mold, and mildew: Dilute SilvaClean® to provide 0.00016% to 0.0014% (1.6 ppm – 14 ppm) silver on fibers or textiles. The treatment level of SilvaClean® for a product will depend on the specific needs of the manufacturer, the textile being treated, and the level and type of performance desired.

Treat textile by soaking in dilute aqueous solution and agitating for at least 2 minutes.

Textile must be clean prior to the application of product. Retreat textile after each laundering.

Store and manage clean linens consistently with the facility's infection control program and best practices.

STORAGE and DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in a safe manner only in areas inaccessible to small children. Store in original container in dark location. Keep container tightly closed when not in use.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, intermediate mixtures, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA regional office for guidance.

Container Handling: RETURN THE CONTAINER TO APPLIED SILVER, INC. in the original outer packaging for appropriate disposal. Do not clean out, refill or dispose of this container.

PRECAUTIONARY STATEMENTS AND FIRST AID

DANGER

Corrosive

Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid breathing spray or mist. Wear goggles, face shield or safety glasses. Wear chemical-resistant apron over coveralls with long-sleeved shirt and long pants, waterproof gloves covering hands, wrists and lower forearms. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse.

First Aid

If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice.
If on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for treatment advice.
If swallowed:	Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a Poison Control Center or doctor for treatment advice.

For emergency information on SilvaClean®, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the Poison Control Center 1-800-222-1222.

Follow the manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters. This product is toxic to fish and aquatic invertebrates.

Optional Marketing Claims

Healthcare: As part of a diligent infection control program, experts recommend that a hospital should seek to reduce or eliminate exposure to pathogens to the greatest extent practical. One practical, inexpensive way to aid in this effort is to use SilvaClean® laundry additive. It provides residual post-laundry activity against *S. aureus* after 6 hours of contact and *K. pneumoniae* after 3 hours of contact when textiles such as bed linens and patient gowns are laundered through the SilvaClean program and properly stored. SilvaClean may be a helpful addition to an Infection Control program. SilvaClean is not a substitute for any existing component of a diligent Infection Control program. Practitioners should continue to implement fully all infection control measures.

Sports: As part of a diligent sports medicine infection control program, experts recommend that athletic programs should seek to reduce or eliminate exposure to pathogens to the greatest extent practical. One practical, inexpensive way to aid in this effort is to use SilvaClean® laundry additive. It provides residual post-laundry activity against *S. aureus* after 6 hours of contact and *K. pneumoniae* after 3 hours of contact when textiles such as bed linens and patient gowns are laundered through the SilvaClean program and properly stored. SilvaClean may be a helpful addition to an Infection Control program. SilvaClean is not a substitute for any existing component of a diligent Infection Control program. Practitioners should continue to implement fully all infection control measures.

Heffernan, Aline

From: Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Tuesday, April 24, 2018 4:51 PM
To: Heffernan, Aline; Bain, Zeno
Subject: RE: 90335-1 - Label revisions
Attachments: 00239970.pdf; 00239972.pdf

Aline:

In an abundance of transparency, I have attached both a redlined (document number 239970) and a clean (document number 239972) version, both with today's date.

Thank you,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA ASIA | EUROPE | THE AMERICAS
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T. 202-266-5031 | F. 202-557-3836 | actagroup.com

From: Heffernan, Aline <heffernan.aline@epa.gov>
Sent: Tuesday, April 24, 2018 4:18 PM
To: Sheryl Lindros Dolan <sdolan@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: 90335-1 - Label revisions

Sheryl,

I need a clean label with this change with today's date on it. Because this is a small change I do not need a red line copy of the label.

Thank you,

Aline

From: Sheryl Lindros Dolan [<mailto:sdolan@actagroup.com>]
Sent: Tuesday, April 24, 2018 4:07 PM
To: Heffernan, Aline <heffernan.aline@epa.gov>; Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: 90335-1 - Label revisions

Aline:

Thank you for your quick turn-around. We are confirming with Applied Silver that the revised statement is acceptable. Assuming that this is the case, please advise what you need from us. We can respond with the clean label, with this one additional change, or we can send in Friday's redlined label with this one additional change also in redlined text, or we can send in Friday's clean label with only this additional change in redline. (There may be other variations on this theme, but please advise what would be the most helpful.)

Thank you,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA ASIA | EUROPE | THE AMERICAS
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T 202-266-5031 | F 202-557-3836 | actagroup.com

From: Heffernan, Aline <heffernan.aline@epa.gov>
Sent: Tuesday, April 24, 2018 3:41 PM
To: Sheryl Lindros Dolan <sdolan@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: 90335-1 - Label revisions

Sheryl,

I was able to connect with Kristen. There is one sentence that we would like you to change on the label. On page two:

Dilute the following volumes of SilvaClean® concentrate volumes per 100 lbs of selected fabric type into 500 or 1000 mL distilled or deionized water and dose as part of the final rinse step in the laundry process to achieve residual bacterial reduction for post-laundry contamination:...

Please remove bacterial reduction and add the word reduction. So it should read:

Dilute the following volumes of SilvaClean® concentrate volumes per 100 lbs of selected fabric type into 500 or 1000 mL distilled or deionized water and dose as part of the final rinse step in the laundry process to achieve residual ~~bacterial reduction~~ for post-laundry contamination reduction:...

Please let me know if you have any questions about this small change.

Thank you,

Aline

From: Sheryl Lindros Dolan [<mailto:sdolan@actagroup.com>]
Sent: Tuesday, April 24, 2018 2:24 PM
To: Heffernan, Aline <heffernan.aline@epa.gov>; Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: 90335-1 - Label revisions

Aline,

Thank you for the update.

Best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA ASIA | EUROPE | THE AMERICAS
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T 202-266-5031 | F 202-557-3836 | actagroup.com

From: Heffernan, Aline <heffernan.aline@epa.gov>
Sent: Tuesday, April 24, 2018 2:21 PM
To: Sheryl Lindros Dolan <sdolan@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: 90335-1 - Label revisions

Sheryl,

The label looks good to me. I want to confer with the efficacy team leader to make sure she agrees with the changes as well. As soon as I have a chance to confer with her I will let you know if we have any comments.

If all goes well, I plan on getting you a stamped label by the end of the week but hopefully it will be finished sooner.

Thanks,

Aline

From: Heffernan, Aline
Sent: Tuesday, April 24, 2018 10:24 AM
To: 'Sheryl Lindros Dolan' <sdolan@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: 90335-1 - Label revisions

Sheryl,

I plan on reviewing your label this afternoon. I will let you know if I have any questions.

Thank you,

Aline

From: Sheryl Lindros Dolan [<mailto:sdolan@actagroup.com>]
Sent: Tuesday, April 24, 2018 10:22 AM
To: Heffernan, Aline <heffernan.aline@epa.gov>; Bain, Zeno <Bain.Zeno@epa.gov>
Subject: FW: 90335-1 - Label revisions

Aline and Zeno:

We wish to confirm AD's receipt of Friday's e-mail. If you could advise regarding the likely timeline for review and comment on the proposed changes, that would be greatly appreciated. We know we still owe you a sanitized copy of the meeting presentation.

As always, please advise if there are any questions or comments.

Best regards,
Sheryl Dolan

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA ASIA | EUROPE | THE AMERICAS
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-266-5031 | F: 202-557-3836 | actagroup.com

From: Sheryl Lindros Dolan
Sent: Friday, April 20, 2018 5:30 PM
To: Aline Heffernan <heffernan.aline@epa.gov>
Cc: Kathryn V. Montague <Montague.kathryn@epa.gov>; Zeno Bain <Bain.zeno@Epa.gov>; Lynn L. Bergeson <lbergeson@actagroup.com>
Subject: RE: 90335-1 - Label revisions

Aline:

Attached are proposed revisions to the label that was submitted on April 12, 2018; both a redlined (document number 239767) and a clean label (document number 239761) are attached. In some places, AD's comments from earlier today were not self-implementing. In other places, Applied Silver is proposing modest tweaks. In all cases, we believe the proposed language is consistent with AD's comments from earlier today.

Regarding container disposal, we note that consistent with the current label language, Applied Silver collects the containers back from its customers, so the customers should not be engaged in any disposal. Additional language is proposed to clarify. We hope this is helpful.

If there are any questions or comments, please call me. We appreciate AD's quick turn around and attention to this submission.

Best regards,
Sheryl Dolan

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA ASIA | EUROPE | THE AMERICAS
2200 Pennsylvania Avenue, NW Suite 100W | Washington D.C. 20037
T: 202-266-5031 | F: 202-557-3836 | actagroup.com

From: Heffernan, Aline <heffernan.aline@epa.gov>
Sent: Friday, April 20, 2018 8:18 AM
To: Sheryl Lindros Dolan <sdolan@lawbc.com>; Montague, Kathryn V. <Montague.Kathryn@epa.gov>
Cc: Lynn L. Bergeson <lbergeson@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: 90335-1 - Agreement needed to renegotiate PRIA due date

Sheryl,

I received a copy of the revised label. It was sent to our efficacy team. Please see the revised efficacy review and the annotated label.

Please let me know if you have any questions on the changes that are being requested.

Thank you,

Aline

From: Sheryl Lindros Dolan [<mailto:sdolan@lawbc.com>]
Sent: Friday, March 30, 2018 12:39 PM

To: Montague, Kathryn V. <Montague.Kathryn@epa.gov>

Cc: Lynn L. Bergeson <lbergeson@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>; Heffernan, Aline <heffernan.aline@epa.gov>

Subject: RE: 90335-1 - Agreement needed to renegotiate PRIA due date

Kay:

Thank you. On behalf of Applied Silver, Inc., we agree to the 60-day extension. We will forward under separate cover a proposed meeting agenda, including the types of information for discussion and meeting participants.

Best regards,
Sheryl

From: Montague, Kathryn V. [mailto:Montague.Kathryn@epa.gov]

Sent: Friday, March 30, 2018 12:27 PM

To: Sheryl Lindros Dolan

Cc: Lynn L. Bergeson; Bain, Zeno; Heffernan, Aline

Subject: 90335-1 - Agreement needed to renegotiate PRIA due date

Good Morning, Sheryl,

Per our discussion, in order to continue consideration of this amendment request and examine the additional information/input from the American Hospital Association that you have described, we request that the PRIA timeframe be extended by 60 days, with a new PRIA due date of June 4, 2018. Please respond to this email to indicate whether or not Applied Silver, Inc., agrees to this new date. I need to have the response no later than Monday, April 2, 2018, in order to begin the renegotiation process within OPP.

Best Regards,
Kay

Kathryn V. Montague
Acting Chief, Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
(703)305-1243




An official website of the United States government
Here's how you know



PRIA Renegotiation

kmontagu 
(/PRIARenegotiation/logout)

PRIA Renegotiation

Information 		
Form Status: Approved		
Decision #	Registration #	Petition #
538139	90335-1	
Chemical Name: *		Company: *
SilvaClean		APPLIED SILVER, INC.
Fee Category:	PRIA Decision Time Frame:	
A570	4M	
Original PRIA Due Date:	Proposed New PRIA Due Date: *	
2018-04-09	2018-06-04	
Previous Negotiated Dates:		
Is "Fix" in-house?:		
<input type="radio"/> Yes <input type="radio"/> No		
<input type="radio"/> NA		
If not, date "Fix" expected:		
2018-04-12		
Negotiated Due Date Reason: 		
Summary of Deficiency Type(s): 		
Describe Interactions with Company(Describe when Contacted and Company's Response including response to Previous Negotiated Due Dates:)		

Registrant attempted to bridge this silver product to a copper product with similar uses for efficacy purposes. The efficacy team does not agree that the products can be bridged. A 75-day letter was sent March 20. Registrant responded March 23 and again on March 29 with a request to renegotiate the PRIA date and meet with the Agency. They have some additional information they would like to present to us and have us consider, which includes information from the American Hospital Association. Registrant agreed to a 60-day renegotiation. A meeting is scheduled for April 12.

"75 Day" Letter Sent? *

Yes, Date Sent

2018-03-20

No and Reason for none?

Rationale for Proposed Due Date:

Allow registrant to present additional information, and allow the efficacy team time to review this information and determine if it changes the decision on bridging of efficacy data.

Registrant Notified that this is the last negotiation: *

Yes

NA

Issue(s) Describe in Detail:

Efficacy team does not agree with bridging rationale for silver laundry sanitizer product that wants to add public health claims. Registrant has some additional information which may provide new insight into the claims/bridging rationale.

Reviewer/Approver Comment(s):

Attachments

eSignature:

Richard Keigwin (RKEIGWIN)
from IO (Host IP Address:
10.202.130.188) on Mon Apr
02 16:38:41 EDT 2018

Audit Trail

2018-03-20

(<http://intranet.epa.gov/pesticides/reference/work@home/index.htm>)

2018-03-20

(<http://intranet.epa.gov/>)

2018-03-20

(<http://www.epa.gov/epafiles/usenotice.htm>)

2018-03-20

(<http://www.epa.gov/>)

2018-03-20

(<http://www.epa.gov/pesticides/>)

2018-03-20

(<http://intranet.epa.gov/pesticides/reference/index.htm>)

2018-03-20

(<http://intranet.epa.gov/pesticides/emergencies/index.htm>)

2018-03-20

(<http://intranet.epa.gov/pesticides/comment/index.htm>)

[A-Z Index \(http://intranet.epa.gov/pesticides/a-z_index.htm\)](http://intranet.epa.gov/pesticides/a-z_index.htm)

For any type of Login problems,
you may email to [EZTech \(mailto:EZTech@epa.gov\)](mailto:EZTech@epa.gov) or call 1-866-411-4EPA (4372).



Applied Silver, Inc. Discussion With EPA's Office of Pesticide Programs April 12, 2018

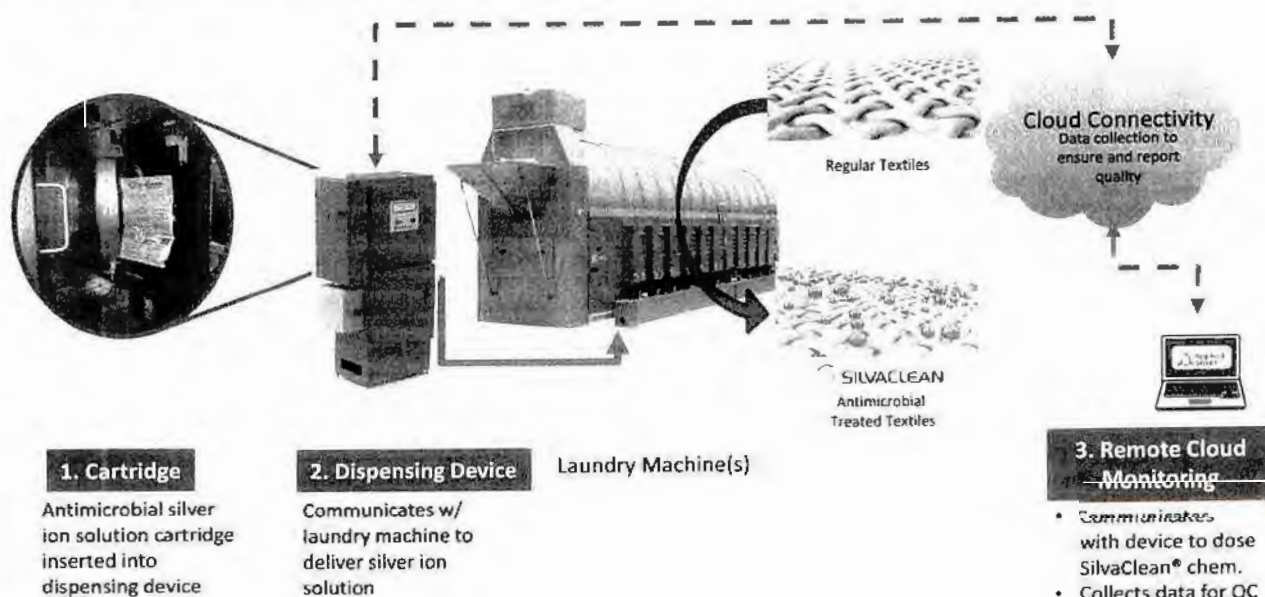
The SilvaClean® System Overview



Antimicrobial Treatment with Quality Assurance

Components:

1. **Cartridge:** containing EPA registered SilvaClean® chemistry
2. **Dispensing device:** linked to laundry machine
3. **Remote cloud monitoring:** system control and data collection

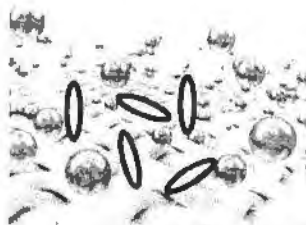


1. SilvaClean chemistry is added to clean laundry during the final rinse cycle of a laundry process



Silver ions stick to fabric until the next laundry cycle

2. Bacteria, mold and mildew are introduced through contact and the environment



Fabric provides a good surface for growth and spread of odor and stain causing bacteria, mold and mildew

3. SilvaClean chemistry provides antimicrobial activity to textiles



Silver ions kill microorganisms through multiple modes of action


Competitive Analyses: Features and Benefits

TECHNOLOGY ATTRIBUTES	Antimicrobial impregnated fabrics (copper, silver)	Fluid repellant fabrics	Disposable privacy curtains	SILVA CLEAN Silver ion antimicrobial textile treatment	Chlorine, quat, peroxide laundry additive	Fluid repellant laundry additive
Sustained Antimicrobial Effect	Degrades over time	Degrades over time	X	✓	Requires Moisture	X
Relative Cost	\$\$\$\$	\$\$\$\$	\$\$\$\$	\$\$\$	\$	\$\$\$
Utilizes Existing Processes and Textile Inventory	X	X	X	✓	X	X
Maintains Look and Feel	X		X	✓	X	X
Designed for All Fabric Types	X	X	X	✓	✓	X

Silver Ions

- Symbol: Ag^+
- Require soak time: < 2 mins
- Presence on fabric: chemical bond
- Mode of action: Oligodynamic
 1. Punctures cell membrane
 2. Deactivates metabolic enzymes (suffocation)
 3. Prevents DNA replication
- Killing requirement: contact

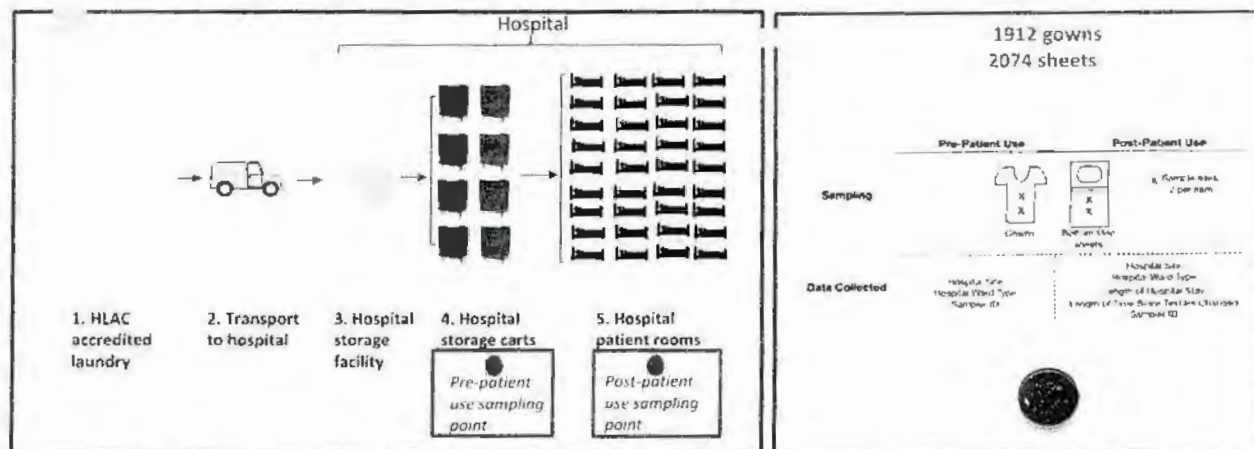
Quaternary Ammonium Compounds

- Symbol: 
- Required soak time: 5 – 8 mins
 - Time provides limited utility due to reality of the laundry process
- Presence on fabric: chemical bond
- Mode of action: Cell lysis
 1. Disrupt cell membrane while in a common liquid solution
- Killing requirement: full wetting for cell lysis

Stanford Study Design: SilvaClean® In-Situ Activity

Study Design

1. The study was conducted at 3 community hospitals sharing a common HLAC accredited laundry
2. Test samples were treated with SilvaClean® chemistry and control samples were untreated
3. Pre-patient sampling was conducted post-laundrying, transportation and storage at hospital
4. Post-patient sampling was conducted immediately after patients vacated the rooms





Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org



Brief Report

Reduction in bacterial contamination of hospital textiles by a novel silver-based laundry treatment

John J. Openshaw MD^{a,*}, William M. Merns BS^b, Gregory V. Lowry PhD^c, Aydin Nazmi PhD^d

^a Division of Infectious Diseases and the Stanford Hospital & Clinics, Stanford University School of Medicine, Stanford, CA

^b Applied Silver, Inc., 2015

^c Center for Environmental Engineering, University of Michigan, Ann Arbor, MI, USA

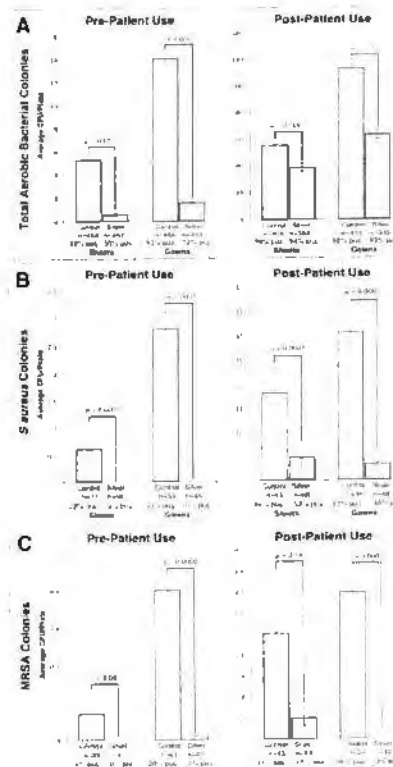
^d Department of Health Services and the Center for Health Systems Research and Analysis, Stanford University, Stanford, CA

S. aureus Analysis (B)

- 100% and 100% *S. aureus* colony count reductions observed on Pre-Patient Use sheets and gowns, respectively.
- 74% and 89% *S. aureus* colony count reductions observed on Post-Patient Use sheets and gowns, respectively.

MRSA Analysis (C)

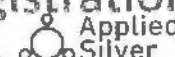
- 100% and 97% MRSA colony count reductions observed on Pre-Patient use sheets and gowns, respectively.
- 80% and 100% MRSA colony count reductions observed on Post-Patient use sheets and gowns, respectively.



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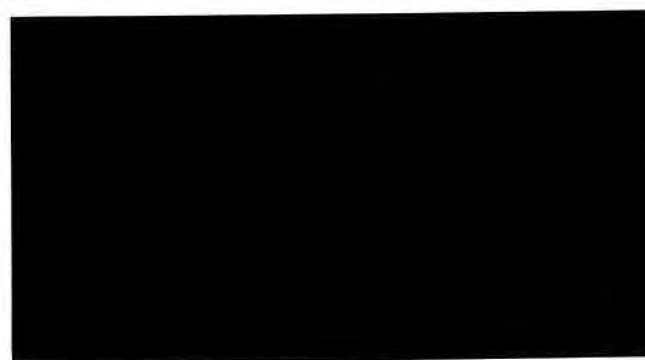
7

Summary of Submitted Results for Pending Registration



AATCC – 100 Laboratory Test Method

Microbe	AATCC-100 Contact Time	% Reduction vs Contact Time
<i>Staphylococcus aureus</i>		
<i>Klebsiella pneumoniae</i>		



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8

Summary of Letters of Support Submitted



- Dr. John Openshaw, MD. Stanford University Department of Medicine.
 - Infectious Disease Physician, Department of Medicine at Stanford University.
 - Faculty Fellow at Center for Innovation in Global Health.
- Christopher G Dawes. Recently retired (March) Stanford Children's Health, Lucile Packard Children's Hospital, Chief Executive Officer.
- Dr. Ronald Loo, MD. Kaiser Permanente, Physician Co-Lead of Health Innovations.
- Sue Barnes, RN, CIC, FAPIC. Former Kaiser Permanente, National Program Leader for Infection Prevention.
- Dr. J Trees Ritter, DO, FIDSA. Medical Director of Infection Control Programs of 5 hospitals.
- Dr. Leopold G Selker, PhD, MBA. Research Scholar in Residence at California Polytechnic State University (Cal Poly).
 - Former President of NorthShore University Health System Research Institute.
 - Former Scholar in Residence at Institute of Medicine – National Academy of Sciences.
- Dr. Aydin Nazmi, PhD. Epidemiologist and Associate Professor of Public Health, Cal Poly.
- Valerie Laktash, MBA, CHFM, CLSS-HC, CEPSS-HC. Placentia Linda Hospital, Director of Facility Services.
- Dr. David Joyner, MD, FACS. Renowned orthopedic surgeon, athlete and sports administrator.

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9

Label Claims Discussion



Goal: Accurately characterize product performance to inform consumers

- Proposed: It provides ongoing residual self-sanitizing activity against *Staphylococcus aureus* and *Klebsiella pneumoniae* on cotton, cotton/polyester blend and microfiber materials until the next laundering event.
- Discussion

Heffernan, Aline

From: Bain, Zeno
Sent: Friday, April 20, 2018 9:26 AM
To: Heffernan, Aline
Subject: FW: Applied Silver Meeting
Attachments: AD Applied Silver 90335-1 Meeting Sign-In.pdf

Thank you

Zeno

From: Bain, Zeno
Sent: Thursday, April 12, 2018 8:08 PM
To: 'Sheryl Lindros Dolan' <sdolan@actagroup.com>
Cc: Lynn L. Bergeson <lbergeson@actagroup.com>; Montague, Kathryn V. <Montague.Kathryn@epa.gov>
Subject: RE: Applied Silver Meeting

Sheryl

Please find the sign in sheet attached from today's meeting.

Thank you

Zeno

From: Sheryl Lindros Dolan [<mailto:sdolan@lawbc.com>] **On Behalf Of** Sheryl Lindros Dolan
Sent: Wednesday, April 11, 2018 1:12 PM
To: Montague, Kathryn V. <Montague.Kathryn@epa.gov>
Cc: Pease, Anita <Pease.Anita@epa.gov>; Bain, Zeno <Bain.Zeno@epa.gov>; Lynn L. Bergeson <lbergeson@actagroup.com>
Subject: Applied Silver Meeting

Kay:

In anticipation of our meeting tomorrow, **April 12, 2018**, with Applied Silver, Inc. (ASI), we are forwarding the attached letters of support from the following U.S. public health industry leaders. In summary, the letters speak to the challenges faced today in healthcare facilities regarding infection control and the value placed on reducing pathogen burden on linens/textiles.

- Dr. John Openshaw, MD. Stanford University Department of Medicine (document number 238491)
 - Infectious Disease Physician, Department of Medicine at Stanford University.
 - Faculty Fellow at Center for Innovation in Global Health.
- Christopher G Dawes. Recently retired (March) Stanford Children's Health, Lucile Packard Children's Hospital, Chief Executive Officer (document number 238747)
- Dr. Ronald Loo, MD. Kaiser Permanente, Physician Co-Lead of Health Innovations (document number 238490)
- Sue Barnes, RN, CIC, FAPIC. Former Kaiser Permanente, National Program Leader for Infection Prevention (document number 238492)
- Dr. J Trees Ritter, DO, FIDSA. Medical Director of Infection Control Programs of 5 hospitals (document number 238717)


- Dr. Leopold G Selker, PhD, MBA. Research Scholar in Residence at California Polytechnic State University (Cal Poly) (document number 238488)
 - Former President of NorthShore University Health System Research Institute.
 - Former Scholar in Residence at Institute of Medicine – National Academy of Sciences.
- Dr. Aydin Nazmi, PhD. Epidemiologist and Associate Professor of Public Health, Cal Poly (document number 238718)
- Valerie Laktash, MBA, CHFM, CLSS-HC, CEPSS-HC. Placentia Linda Hospital, Director of Facility Services (document number 238487)
- Dr. David Joyner, MD, FACS. Renowned orthopedic surgeon, athlete and sports administrator (document number 238486)

We will bring hard copies of the letters with us tomorrow but wished to forward them ahead of time.

We look forward to our discussion tomorrow.

Best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

 **ACTA GROUP**
2200 Pennsylvania Avenue, NW Suite 100W | Washington, D.C. 20037
T 202-266-5031 | F 202-557-3836 | actagroup.com

Heffernan, Aline

From: Bain, Zeno
Sent: Friday, April 20, 2018 9:27 AM
To: Heffernan, Aline
Subject: FW: Applied Silver, Inc.

Thank you

Zeno

From: Bain, Zeno
Sent: Thursday, April 12, 2018 2:08 PM
To: 'Sheryl Lindros Dolan' <sdolan@actagroup.com>
Cc: Montague, Kathryn V. <Montague.Kathryn@epa.gov>
Subject: RE: Applied Silver, Inc.

Sheryl

Thank you for sending this over quickly. I'm forwarding it to efficacy now for review.

Thank you

Zeno

From: Sheryl Lindros Dolan [mailto:sdolan@actagroup.com]
Sent: Thursday, April 12, 2018 2:00 PM
To: Bain, Zeno <Bain.Zeno@epa.gov>
Cc: Montague, Kathryn V. <Montague.Kathryn@epa.gov>
Subject: Applied Silver, Inc.

Zeno:

On behalf of Applied Silver, Inc., thank you very much for today's productive meeting.

Attached is a revised label, as discussed. Based on today's meeting, we have revised language in the first paragraph, when compared with the proposed label that was included originally in the amendment application. The redlined version (document number 238911) shows net proposed redlined changes to the currently-approved label. If helpful, we also attach a clean version of the revised label with all the redlined changes accepted (document number 238922).

As always, please advise if there are any questions or comments.

Best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA

2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T 202-266-5031 | F 202-557-3836 actagroup.com

Heffernan, Aline

From: Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Thursday, April 12, 2018 8:27 AM
To: Montague, Kathryn V.; Bain, Zeno
Subject: RE: Applied Silver Meeting

Thank you, will do!

Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA

AMERICAN THERAPEUTIC ALLIANCE

2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T 202-266-5031 | F 202-557-3836 | actagroup.com

From: Montague, Kathryn V. [mailto:Montague.Kathryn@epa.gov]
Sent: Thursday, April 12, 2018 8:16 AM
To: Sheryl Lindros Dolan; Bain, Zeno
Subject: RE: Applied Silver Meeting

Hi, Sheryl,

There will be a projector available. Aline is out of the office, and I have a 10:00 meeting, so please call Zeno from the lobby when you arrive, 703-347-8102.

Best Regards,
Kay

From: Sheryl Lindros Dolan [mailto:sdolan@actagroup.com]
Sent: Thursday, April 12, 2018 8:02 AM
To: Montague, Kathryn V. <Montague.Kathryn@epa.gov>; Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: Applied Silver Meeting

Kay and Zeno:

Good morning.

Given the nature of today's meeting, we expect the majority of the time will be spent in discussion (consistent with the proposed agenda). We do have a few slides to start to confirm that we are on the same page re: the product and to provide visual reference. We will bring them as handouts but will also have them on a laptop if projection capability is available.

Thank you,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA

AMERICAN THERAPEUTIC ALLIANCE

2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037

From: Montague, Kathryn V. [mailto:Montague.Kathryn@epa.gov]
Sent: Wednesday, April 11, 2018 1:17 PM
To: Sheryl Lindros Dolan
Cc: Pease, Anita; Bain, Zeno; Lynn L. Bergeson
Subject: RE: Applied Silver Meeting

Thank you, Sheryl, I will make sure these are forwarded to everyone attending tomorrow's meeting.

Best Regards,
Kay

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Cc: Pease, Anita <Pease.Anita@epa.gov>; Bain, Zeno <Bain.Zeno@epa.gov>; Lynn L. Bergeson <lbergeson@actagroup.com>
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Best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA
2200 Pennsylvania Avenue NW Suite 100W | Washington, D.C. 20037

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Thank you,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA ASSOCIATION OF APPLIED SILVER TECHNOLOGISTS

2200 Pennsylvania Avenue NW Suite 100W | Washington D.C. 20037
T 202-266-5031 | F 202-557-3836 | actagroup.com

From: Montague, Kathryn V. [mailto:Montague.Kathryn@epa.gov]
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Cc: Pease, Anita; Bain, Zeno; Lynn L. Bergeson
Subject: RE: Applied Silver Meeting

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 - Infectious Disease Physician, Department of Medicine at Stanford University.
 - Faculty Fellow at Center for Innovation in Global Health.

- Christopher G Dawes. Recently retired (March) Stanford Children's Health, Lucile Packard Children's Hospital, Chief Executive Officer (document number 238747)
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- Sue Barnes, RN, CIC, FAPIC. Former Kaiser Permanente, National Program Leader for Infection Prevention (document number 238492)
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Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT



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T 202-266-5031 | F 202-557-3836 actagroup.com

Heffernan, Aline

From: Sheryl Lindros Dolan <sdolan@lawbc.com> on behalf of Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Wednesday, April 11, 2018 1:16 PM
To: Bain, Zeno
Cc: Montague, Kathryn V.
Subject: RE: Meeting Agenda

Zeno:

Thank you very much.

I realize that I made a significant omission in my e-mail earlier. We also will be joined tomorrow by Mr. William (Bill) Jordan, who of course you will know from his many years in the Office of Pesticide Programs. Bill has been working on this matter for some time.

Best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA ACTA Environmental Solutions

2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-266-5031 | F: 202-557-3836 | actagroup.com

From: Bain, Zeno [<mailto:Bain.Zeno@epa.gov>]
Sent: Wednesday, April 11, 2018 11:28 AM
To: Sheryl Lindros Dolan
Subject: RE: Meeting Agenda

Hi Sheryl

EPA attendees include:

Montague, Kathryn;
Willis, Kristen;
Weiss, Steven;
Mitchell, Emily;
Pease, Anita;
Bain, Zeno

Thank you

Zeno

From: Sheryl Lindros Dolan [<mailto:sdolan@lawbc.com>] On Behalf Of Sheryl Lindros Dolan
Sent: Wednesday, April 11, 2018 9:57 AM
To: Montague, Kathryn V. <Montague.Kathryn@epa.gov>
Cc: Bain, Zeno <Bain.Zeno@epa.gov>; Lynn L. Bergeson <lbergeson@actagroup.com>
Subject: Meeting Agenda

Kay:

On behalf of Applied Silver, Inc. (ASI), we forward the attached proposed agenda for tomorrow's meeting.

The following will attend the meeting for ASI:

- Sean D. Morham, Chief Executive Officer
- Elizabeth Hutt Pollard, Executive Chair (via telephone)
- Lynn L. Bergeson, The Acta Group (Acta)
- Sheryl L. Dolan, Acta

Please advise who will attend for the U.S. Environmental Protection Agency, Office of Pesticide Programs.

Thank you and best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA

2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T 202-266-5031 | F 202-557-3836 actagroup.com

Heffernan, Aline

From: Sheryl Lindros Dolan <sdolan@lawbc.com> on behalf of Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Wednesday, April 11, 2018 1:12 PM
To: Montague, Kathryn V.
Cc: Pease, Anita; Bain, Zeno; Lynn L. Bergeson
Subject: Applied Silver Meeting
Attachments: 00238491.pdf; 00238747.pdf; 00238490.pdf; 00238492.pdf; 00238717.pdf; 00238488.pdf; 00238718.pdf; 00238487.pdf; 00238486.pdf

Kay:

In anticipation of our meeting tomorrow, **April 12, 2018**, with Applied Silver, Inc. (ASI), we are forwarding the attached letters of support from the following U.S. public health industry leaders. In summary, the letters speak to the challenges faced today in healthcare facilities regarding infection control and the value placed on reducing pathogen burden on linens/textiles.

- Dr. John Openshaw, MD. Stanford University Department of Medicine (document number 238491)
 - Infectious Disease Physician, Department of Medicine at Stanford University.
 - Faculty Fellow at Center for Innovation in Global Health.
- Christopher G Dawes. Recently retired (March) Stanford Children's Health, Lucile Packard Children's Hospital, Chief Executive Officer (document number 238747)
- Dr. Ronald Loo, MD. Kaiser Permanente, Physician Co-Lead of Health Innovations (document number 238490)
- Sue Barnes, RN, CIC, FAPIC. Former Kaiser Permanente, National Program Leader for Infection Prevention (document number 238492)
- Dr. J Trees Ritter, DO, FIDSA. Medical Director of Infection Control Programs of 5 hospitals (document number 238717)
- Dr. Leopold G Selker, PhD, MBA. Research Scholar in Residence at California Polytechnic State University (Cal Poly) (document number 238488)
 - Former President of NorthShore University Health System Research Institute.
 - Former Scholar in Residence at Institute of Medicine – National Academy of Sciences.
- Dr. Aydin Nazmi, PhD. Epidemiologist and Associate Professor of Public Health, Cal Poly (document number 238718)
- Valerie Laktash, MBA, CHFM, CLSS-HC, CEPSS-HC. Placentia Linda Hospital, Director of Facility Services (document number 238487)
- Dr. David Joyner, MD, FACS. Renowned orthopedic surgeon, athlete and sports administrator (document number 238486)

We will bring hard copies of the letters with us tomorrow but wished to forward them ahead of time.

We look forward to our discussion tomorrow.

Best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA

2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
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Heffernan, Aline

From: Sheryl Lindros Dolan <sdolan@lawbc.com> on behalf of Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Wednesday, April 11, 2018 9:57 AM
To: Montague, Kathryn V.
Cc: Bain, Zeno; Lynn L. Bergeson
Subject: Meeting Agenda
Attachments: 00238472.pdf

Kay:

On behalf of Applied Silver, Inc. (ASI), we forward the attached proposed agenda for tomorrow's meeting.

The following will attend the meeting for ASI:

- Sean D. Morham, Chief Executive Officer
- Elizabeth Hutt Pollard, Executive Chair (via telephone)
- Lynn L. Bergeson, The Acta Group (Acta)
- Sheryl L. Dolan, Acta

Please advise who will attend for the U.S. Environmental Protection Agency, Office of Pesticide Programs.

Thank you and best regards,
Sheryl

SHERYL LINDROS DOLAN
SENIOR REGULATORY CONSULTANT

ACTA AN ACT GROUP COMPANY

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Heffernan, Aline

From: Sheryl Lindros Dolan <sdolan@lawbc.com>
Sent: Friday, March 30, 2018 12:39 PM
To: Montague, Kathryn V.
Cc: Lynn L. Bergeson; Bain, Zeno; Heffernan, Aline
Subject: RE: 90335-1 - Agreement needed to renegotiate PRIA due date

Kay:

Thank you. On behalf of Applied Silver, Inc., we agree to the 60-day extension. We will forward under separate cover a proposed meeting agenda, including the types of information for discussion and meeting participants.

Best regards,
Sheryl

From: Montague, Kathryn V. [mailto:Montague.Kathryn@epa.gov]
Sent: Friday, March 30, 2018 12:27 PM
To: Sheryl Lindros Dolan
Cc: Lynn L. Bergeson; Bain, Zeno; Heffernan, Aline
Subject: 90335-1 - Agreement needed to renegotiate PRIA due date

Good Morning, Sheryl,

Per our discussion, in order to continue consideration of this amendment request and examine the additional information/input from the American Hospital Association that you have described, we request that the PRIA timeframe be extended by 60 days, with a new PRIA due date of June 4, 2018. Please respond to this email to indicate whether or not Applied Silver, Inc., agrees to this new date. I need to have the response no later than Monday, April 2, 2018, in order to begin the renegotiation process within OPP.

Best Regards,
Kay

Kathryn V. Montague
Acting Chief, Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
(703)305-1243

Heffernan, Aline

From: Sheryl Lindros Dolan <sdolan@actagroup.com>
Sent: Thursday, March 29, 2018 12:03 PM
To: Heffernan, Aline
Cc: Bain, Zeno; Montague, Kathryn V.; Weiss, Steven; Lynn L. Bergeson
Subject: RE: Label Amendment Reg. No. 90335-1 75 day letter

Importance: High

Aline:

In its March 20, 2018, letter, EPA clearly offered three options, and directed Applied Silver, Inc. (ASI) to respond within six days. One option was to establish a new PRIA due date. ASI responded in three days with a letter delivered via e-mail and by hand. In the letter, ASI elected the, "Establish a new due date" option, and provided an interim extension of the PRIA date from April 9 until April 24, to permit time to meet. Please clarify if EPA is now rescinding the offer that we have already accepted.

We strongly disagree that there is no benefit to meeting, and there is considerable disagreement on the claims issue. We restate our request to keep the meeting, currently scheduled for Thursday, April 12, 2018, at 11:00 a.m., on the calendar.

Sincerely,

SHERYL LINDROS DOLAN

ACTA

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From: Heffernan, Aline [mailto:heffernan.aline@epa.gov]
Sent: Thursday, March 29, 2018 11:31 AM
To: Sheryl Lindros Dolan
Cc: Bain, Zeno; Montague, Kathryn V.; Weiss, Steven; Lynn L. Bergeson
Subject: RE: Label Amendment Reg. No. 90335-1 75 day letter

Sheryl,

I think there is some confusion. The 75 day letter does not change the PRIA date. The PRIA is due on April 9.

While there may be benefits to your product without acceptable efficacy data, we cannot allow the claims on the label. At this time I strongly recommend that you withdraw the amendment and submit again when you have adequate efficacy data. We will cancel the meeting unless you believe that the data was submitted with the PRIA was misinterpreted.

At this time we will not renegotiate the PRIA due date but we are open to offering you a not grant so you can submit new efficacy data. The not grant does take the action off the PRIA clock so there are no longer any PRIA due dates.

Thank you,

Aline

From: Sheryl Lindros Dolan [mailto:sdolan@actagroup.com]
Sent: Wednesday, March 28, 2018 3:58 PM
To: Heffernan, Aline <heffernan.aline@epa.gov>
Cc: Bain, Zeno <Bain.Zeno@epa.gov>; Montague, Kathryn V. <Montague.Kathryn@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>; Lynn L. Bergeson <lbergeson@actagroup.com>
Subject: RE: Label Amendment Reg. No. 90335-1 75 day letter

Aline:

It appears from this initial response that the efficacy team is very aligned with the existing quat technology and not acknowledging the beneficial distinctions offered by the silver technology. The supporting study with Stanford University, which you stated AD does not have capacity to review, supports the benefits. As Applied Silver, Inc. (ASI) discussed with AD in its October 24, 2017, meeting, these are the benefits that ASI wishes to further explore. The need for and the interest in this technology is significant in the public health community. ASI can provide significant support from a range of public health officials in this regard.

Among the important distinctions from legacy technologies, we note that hospital laundries currently and will continue to sanitize textiles as part of the laundry process as they have always done. This technology is not a substitute for that but, consistent with its current application for non-public health uses, it is used in conjunction, as a final rinse. We also note, as discussed in the submission, the silver technology does not require a wetting or soiling event to permit efficacy, but offers its benefits under dry conditions.

We fail to see how we can progress with anything short of a meeting. AD certainly seemed to understand the technology and was willing to progress both these discussions and the first of successive planned registration amendments at the October 24, 2017, meeting. As it stands, with its March 23, 2018, letter, timely submitted, ASI has extended the current PRIA date until April 24, 2018. It renews its request to meet as scheduled.

Best regards,

SHERYL LINDROS DOLAN

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
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From: Heffernan, Aline [mailto:heffernan.aline@epa.gov]
Sent: Wednesday, March 28, 2018 7:38 AM
To: Sheryl Lindros Dolan
Cc: Bain, Zeno
Subject: RE: Label Amendment Reg. No. 90335-1 75 day letter

Sheryl,

I hope you are doing well. I have some information for you from the efficacy team. Please see the information below.

While there is similarity to copper in terms of the claims that they want to make (residual self-sanitizing activity) the products are very different. The most obvious difference is that copper is hard surface designed to be installed and used for months to years while the product application for SilvaClean is for laundry, a soft surface that needs to be re-treated with frequency.

We have not allowed sanitizer claims (3-log) for contact times greater than 5 minutes with the exception of products like the copper products due to their unique uses. For copper products, the maximum contact time is 2 hours. The efficacy data for Silvacleen demonstrates that a 3-log reduction was not achieved until 3+ hours, so it does not even meet the bar for copper products. In addition, for the copper products the efficacy testing incorporates a robust wear process that is not a component of the residual laundry protocol.

Note: For the Mason product (Reg. No. 6836-63) that was noted by the registrant as a similar product that they would like to have the same claims as, that product did achieve a 3-log reduction in 5 minutes.

At this point, with the existing data there is no additional information that would make the claims acceptable.

Based on the information from the efficacy team at this time we don't believe that a meeting would be a good use for everyone's time. There are a few options to move forward at this point. You can withdraw the amendment, you can request a not grant and produce new efficacy data or we can deny the action.

Due to the fact that the 75 day letter that was sent does not close the PRIA we need a decision as soon as possible. Do you think you can get back to me with your decision on how to move forward by tomorrow at 1?

Please let me know if you have any questions.

Thank you,

Aline

From: Sheryl Lindros Dolan [<mailto:sdolan@actagroup.com>]
Sent: Monday, March 26, 2018 5:24 PM
To: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: Label Amendment Reg. No. 90335-1 75 day letter

Thank you.

I am have accepted the meeting date/time and am confirming that works.

Best regards,

SHERYL LINDROS DOLAN

ACTA AGRO-chemicals Technology Association

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-266-5031 | F: 202-557-3836 | actagroup.com

From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]
Sent: Monday, March 26, 2018 11:12 AM
To: Sheryl Lindros Dolan; Bain, Zeno
Cc: Montague, Kathryn V.; Weiss, Steven; Lynn L. Bergeson
Subject: RE: Label Amendment Reg. No. 90335-1 75 day letter

Sheryl,

There is an updated DER for the review. Please see attached review.

Thank you,

Aline

From: Heffernan, Aline
Sent: Friday, March 23, 2018 3:09 PM
To: 'Sheryl Lindros Dolan' <sdolan@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>

Cc: Montague, Kathryn V. <Montague.Kathryn@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>; Lynn L. Bergeson <lbergeson@actagroup.com>

Subject: RE: Label Amendment Reg. No. 90335-1 75 day letter

Sheryl,

Thank you and I understand. Please email or call me to schedule the meeting.

Thank you,

Aline

From: Sheryl Lindros Dolan [mailto:sdolan@actagroup.com]

Sent: Friday, March 23, 2018 2:51 PM

To: Heffernan, Aline <heffernan.aline@epa.gov>; Bain, Zeno <Bain.Zeno@epa.gov>

Cc: Montague, Kathryn V. <Montague.Kathryn@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>; Lynn L. Bergeson <lbergeson@actagroup.com>

Subject: RE: Label Amendment Reg. No. 90335-1 75 day letter

Aline:

We confirm receipt of EPA's letter.

Attached is a letter from Applied Silver, Inc., responding to the 75-day letter. I will follow up Monday concerning the meeting request.

Thank you,

SHERYL LINDROS DOLAN

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T 202-266-5031 | F 202-557-3836 | actagroup.com

From: Heffernan, Aline [mailto:heffernan.aline@epa.gov]

Sent: Friday, March 23, 2018 2:14 PM

To: Sheryl Lindros Dolan; Bain, Zeno

Cc: Montague, Kathryn V.

Subject: RE: Label Amendment Reg. No. 90335-1 75 day letter

Sheryl,

I hope you are doing well. Can you please confirm the receipt of this letter.

Thank you,

Aline

From: Heffernan, Aline

Sent: Tuesday, March 20, 2018 4:28 PM

To: 'Sheryl Lindros Dolan' <sdolan@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>

Cc: Montague, Kathryn V. <Montague.Kathryn@epa.gov>

Subject: Label Amendment Reg. No. 90335-1 75 day letter

Sheryl,

Please see the attached efficacy review and 75 day letter. Please let me know if you have any questions or concerns.

Thank you,

Aline

From: Heffernan, Aline

Sent: Tuesday, March 06, 2018 10:29 AM

To: 'Sheryl Lindros Dolan' <sdolan@actagroup.com>; Bain, Zeno <Bain.Zeno@epa.gov>

Cc: Montague, Kathryn V. <Montague.Kathryn@epa.gov>

Subject: RE: Pending Label Amendment for EPA Reg. No. 90335-1

Sheryl,

The Predecisional date is 3/26/2018. By that date, we will send a pre-decisional letter and a completely annotated label.

Thank you,

Aline

From: Sheryl Lindros Dolan [<mailto:sdolan@actagroup.com>]

Sent: Tuesday, March 06, 2018 10:19 AM

To: Heffernan, Aline <heffernan.aline@epa.gov>; Bain, Zeno <Bain.Zeno@epa.gov>

Cc: Montague, Kathryn V. <Montague.Kathryn@epa.gov>

Subject: RE: Pending Label Amendment for EPA Reg. No. 90335-1

Aline,

Many thanks for your rapid response.

Indeed, we expect the heavy lifting for the label review will be with respect to the efficacy claims. Applied Silver has had an ongoing dialog with EPA and considerable thought went into the white paper submitted as part of the October 24, 2017, meeting. John Hebert remarked with regret not including more RMB I people at the October 24, 2017, meeting. We just wished to raise this on the radar now to anticipate and manage workload later this month.

Thank you and best regards,

SHERYL LINDROS DOLAN

ACTA AGRICULTURAL CHEMICAL TECHNOLOGIES

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From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]

Sent: Tuesday, March 06, 2018 10:13 AM

To: Sheryl Lindros Dolan; Bain, Zeno

Cc: Montague, Kathryn V.

Subject: RE: Pending Label Amendment for EPA Reg. No. 90335-1

Sheryl,

Thank you for contacting us. We are still waiting on the efficacy review but that should be completed soon. I've followed up with the efficacy team leader and reviewer to get an update.

Based on what was submitted the public health marketing claims will be reviewed. The attached letter has several comments on the label that excludes any comments on the efficacy review. Including the new marketing claims at the end of the label. It will be discussed internally with the efficacy team if those are considered false and misleading based on my review and the efficacy review.

Please do not consider the annotated label to be a complete label review. It will not be completed until the efficacy review is finished.

Let me know if you have any questions or concerns.

Thank you,
Aline

From: Sheryl Lindros Dolan [mailto:sdolan@actagroup.com]
Sent: Tuesday, March 06, 2018 9:47 AM
To: Bain, Zeno <Bain.Zeno@epa.gov>
Cc: Montague, Kathryn V. <Montague.Kathryn@epa.gov>; Heffernan, Aline <heffernan.aline@epa.gov>
Subject: Pending Label Amendment for EPA Reg. No. 90335-1

Zeno:


When we spoke previously regarding the pending label amendment for Applied Silver, Inc.'s (ASI) SilvaClean product, EPA Reg. No. 90335-1, you stated that you expect to receive the science reviews for the pending application in the second half of March. RMB I then will have a couple of weeks to review the proposed label claims by the April 9, 2018, PRIA deadline.

As regrettably no one on this e-mail participated in ASI's October 24, 2017, pre-submission meeting with then Acting Antimicrobial Division (AD) Director Steve Weiss, we wish to highlight that a review of the proposed claims for the pending application may require more than the standard level of effort. Volume 1 of the submission (MRID 335-1) includes the October 24, 2017, meeting minutes, a copy of the substantial white paper submitted prior to the meeting, and a discussion of the proposed label claims. ASI wishes to raise for RMB I's consideration whether it wishes to start its review of the proposed claims and possibly a related discussion with ASI, as needed, prior to the end of this month.

ASI thanks AD for its ongoing engagement and responsiveness.

Best regards,

SHERYL LINDROS DOLAN


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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON,
DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

March 07, 2018
Revised April 17, 2018

MEMORANDUM

Subject: Efficacy Review for SilvaClean, EPA Reg. No. 90335-1; DP Barcode: D444670; Submission #: 1012169; E-Sub # 24426.

From: Kristen Willis, Ph.D.
Efficacy Team Leader *Kristen Willis*
Product Science Branch
Antimicrobials Division (7510P)

To: Zeno Bain, PM33 / Aline Heffernan
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Formulation from the Label:

Active Ingredients	% by wt.
Silver	22.5 %
Other Ingredients:	<u>77.5 %</u>
Total	100.0 %

I. BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment

Currently registered efficacy claim(s): application to textiles after each laundering to protect fibers against stain- and odor-causing bacteria, mold, and mildew.

Requested action(s): Add residual self-sanitizing laundry additive claim

Documents considered in this review:

- Letter from applicant to EPA dated November 17, 2017
- Application for Pesticide (EPA form 8570-1) dated November 17, 2017
- Certification with Respect to Citation of 1ata (EPA Form 8570-34) dated November 17, 2017
- Data Matrix (EPA Form 8570-35) dated November 17, 2017
- 7 efficacy studies (MRID 504405-01-504405-08)
- 1 additional MRID dated 01/23/2018 with supplemental information to address the technical screen (MRID 50504501)
- Proposed label dated November 17, 2017

II. PROPOSED DIRECTIONS FOR USE

For ongoing residual self-sanitizing activity against *Klebsiella pneumoniae*, and *Staphylococcus aureus*, on cotton, cotton/polyester blends, and microfiber fabrics and for preservation against stain- and odor causing bacteria, mold and mildew use as directed.

SilvaClean® is a concentrate that must be diluted with distilled or deionized water before use.

Ongoing residual self-sanitizing: Dilute the following volumes of SilvaClean® concentrate volumes per 100 lbs of selected fabric type into 500 or 1000 mL distilled or deionized water and dose as part of the final rinse step in the laundry process to achieve residual self-sanitization:

- 0.024 oz per 100 lbs cotton
- 0.032 oz per 100 lbs cotton/poly blend
- 0.048 oz per 100 lbs microfiber

Add the diluted solution into the final rinse cycle of a laundry process. Allow to soak with fabric at least 2 minutes.

III. STUDY SUMMARIES

1. MRID 504405-02 "Treating Fabric with Self-Sanitizing Laundry Test Solution" for Test Solution, by Sean Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1777.

This study was conducted to treat three fabric types, Microfiber (100% Polyester, lot: 286-E), Cotton (100%, lot: 286-A), and Cotton/Poly Blend (55% Cotton, 45% Polyester, lot: 286-B), with "Test Solution" (lots: 170821-1, 170821-2, and 170821-3) during laundry, according to Microchem Laboratory protocol P1937 (copy provided). The product, adjusted to the LCL concentration, was diluted to 0.0000310 ration in 200ppm hard tap

water for polyester, 0.0000155 for cotton, and 0.0000207 for blend. Product was applied during 23-minute rinse cycle with 2-minute soaking time; and 55-minute drying time.

Treated fabrics were assigned the following lot numbers:

Treated Microfiber Fabric: M-1-11SEP2017A, M-2-11SEP2017A, and M-3-11SEP2017A

Treated Cotton Fabric: C-1-12SEP2017A, C-2-12SEP2017A, and C-3-12SEP2017A

Treated Cotton/Poly Blend Fabric: CP-1-12SEP2017A, CP-2-12SEP2017A, and CP-3-12SEP2017A

2. MRID 504405-03 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *S. aureus*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1810.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (C-1-12SEP2017A, C-2-12SEP2017A, and C-3-12SEP2017A) of "Treated Cotton Fabric", were tested according to Microchem Protocol P1938 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

3. MRID 504405-04 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *S. aureus*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1813.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (CP-1-12SEP2017A, CP-2-12SEP2017A, and CP-3-12SEP2017A) of "Treated Cotton/Poly Blend Fabric", were tested according to Microchem Protocol PP1994 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, 24 hours, 48 hours, and 72 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

4. MRID 504405-05 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *S. aureus*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1814.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (M-1-11SEP2017A, M-2-11SEP2017A, and M-3-11SEP2017A) of "Treated Microfiber Fabric", were tested according to Microchem Protocol P2005 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

5. MRID 504405-06 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *K. pneumoniae*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1811.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Three lots (C-1-12SEP2017A, C-2-12SEP2017A, and C-3-12SEP2017A) of "Treated Cotton Fabric", were tested according to Microchem Protocol P1979 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24

hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 \pm 4 hours and all study controls were incubated for 48 \pm 2 hours at 36 \pm 1°C.

6. MRID 504405-07 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *K. pneumoniae*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1812.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Three lots (CP-1-12SEP2017A, CP-2-12SEP2017A, and CP-3-12SEP2017A) of "Treated Cotton/Poly Blend Fabric", were tested according to Microchem Protocol PP1993 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at 36 \pm 1°C for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, 24 hours, 48 hours, and 72 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 \pm 4 hours and all study controls were incubated for 48 \pm 2 hours at 36 \pm 1°C.

7. MRID 504405-08 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *K. pneumoniae*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1815.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Three lots (M-1-11SEP2017A, M-2-11SEP2017A, and M-3-11SEP2017A) of "Treated Microfiber Fabric", were tested according to Microchem Protocol P2006 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at 36 \pm 1°C for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 \pm 4 hours and all study controls were incubated for 48 \pm 2 hours at 36 \pm 1°C.

V. RESULTS

MRID	Organism	Lot #	Controls	% Reduction							
				30 min.	1 hr.	2 hrs.	3 hrs.	6 hrs.	24 hrs.	48 hrs.	72 hrs.
Treated Cotton Fabrics											
50440 5-03	Staphylococcus aureus (ATCC 6538)	C-1-12SEP2017A	3.6 x 10 ⁵ 1.03 x 10 ⁶	56.09	89.43	98.22	99.86	>99.99	>99.99	-	-
		C-2-12SEP2017A		65.90	75.99	99.16	99.54	>99.9	>99.99	-	-
		C-3-12SEP2017A		57.66	90.60	98.49	>99.9	>99.9	>99.99	-	-
50440 5-06	Klebsiella pneumoniae (ATCC 4352)	C-1-12SEP2017A	5.25 x 10 ⁵ 1.09 x 10 ⁶	32.56	38.61	99.77	>99.9 g	>99.99 99	>99.99 999	-	-
		C-2-12SEP2017A		32.09	69.24	99.68	>99.9 g	>99.99 9	>99.99 999	-	-
		C-3-12SEP2017A		0	45.32	99.68	>99.9 g	>99.99 99	>99.99 999	-	-
Treated Microfiber Fabrics											
50440 5-05		M-1-11SEP2017A	4.5 x 10 ⁵	61.36	95.83	99.70	>99.9	>99.9	-	-	-

MRID	Organism	Lot #	Controls	% Reduction							
				30 min.	1 hr.	2 hrs.	3 hrs.	6 hrs.	24 hrs.	48 hrs.	72 hrs.
	<i>Staphylococcus aureus</i> (ATCC 6538)	M-2-11SEP2017A	4.33 x 10 ⁵	41.59	97.45	99.56	99.51	>99.9	-	-	-
		M-3-11SEP2017A		72.04	91.79	99.49	>99.9	>99.9	-	-	-
50440 5-08	<i>Klebsiella pneumoniae</i> (ATCC 4352)	M-1-11SEP2017A	3.58 x 10 ⁵	24.70	98.14	>99.9	>99.9	>99.99	>99.99	-	-
		M-2-11SEP2017A	1.79 x 10 ⁵	54.65	97.23	>99.9	>99.9	>99.99	>99.99	-	-
		M-3-11SEP2017A	10 ⁵	86.04	99.77	>99.9	>99.9	>99.99	>99.99	-	-
Treated Cotton/Poly Blend Fabrics											
50440 5-04	<i>Staphylococcus aureus</i> (ATCC 6538)	CP-1-12SEP2017A	5.89 x 10 ⁵	46.29	65.06	95.07	99.03	>99.99	>99.99	>99.9999	>99.9999
		CP-2-12SEP2017A	6.71 x 10 ⁵	53.33	98.44	99.87	99.18	>99.99	>99.99	>99.9999	>99.9999
		CP-3-12SEP2017A	10 ⁵	35.05	70.17	99.82	99.55	99.99	>99.99	>99.9999	>99.9999
50440 5-07	<i>Klebsiella pneumoniae</i> (ATCC 4352)	CP-1-12SEP2017A	1.57 x 10 ⁶	40.10	66.92	99.88	>99.99	>99.99	>99.99	>99.9999	>99.9999
		CP-2-12SEP2017A	1.04 x 10 ⁶	37.87	96.39	>99.99	>99.99	>99.99	>99.99	>99.9999	>99.9999
		CP-3-12SEP2017A		50.25	92.48	>99.99	>99.99	>99.99	>99.99	>99.9999	>99.9999

VI. CONCLUSIONS

MRID #	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support label claims?
504405-02 ~ 504405-08	Residual Bacterial Reduction for Post Laundry Contaminations	Laundered Dried Fabrics/Textiles	0.0000310 ration for polyester, 0.0000155 for cotton, and 0.0000207 for blend.	23-minute rinse cycle with 2-minute soaking time; and 55-minute drying time	No	200ppm hard tap water	<ul style="list-style-type: none"> <i>Staphylococcus aureus</i> (ATCC 6538) <i>Klebsiella pneumoniae</i> (ATCC 4352) 	No

VII. LABEL

Proposed Label dated November 17, 2017

1. The proposed label claims that the product, SilvaClean (EPA Reg. No. 90335-1), provides ongoing residual self-sanitizing activity against *Staphylococcus aureus* and *Klebsiella pneumoniae* on cotton, cotton/polyester blend and microfiber materials until the next laundering event. **These claims are not acceptable as they are not supported by the submitted data.**

All claims for residual self-sanitizing activity should be removed. The following provide rationale as to why these claims are not acceptable:

- To make label claims as a "Sanitizer" a product should demonstrate a 3-log reduction at a contact time ≤5 minutes.
 - o A 3-log reduction was not achieved for any of the fabric types at a 30-minute contact time
- Claims for "ongoing" are synonymous with continuous and testing to support these claims should include re-inoculation steps.

2. The applicant must make the following changes to the proposed label, as appropriate:

- Remove all claims and associated directions for use as a "residual self-sanitizer"
- Remove all claims for "self-sanitizing" and any mention of specific microorganisms (e.g. *Staphylococcus aureus* and *Klebsiella pneumoniae*).
- Remove the optional marketing claims for healthcare and sports

The registrant submitted a revised label on 04/12/2018 after a meeting with EPA that same day. In attendance at the meeting for EPA were the following individuals: Anita Pease, Steve Weiss, Emily Mitchell, Kay Montague, Zeno Bain and Kristen Willis.

Proposed Label dated April 12, 2017

- 1) On pages 1-3 and 5 of the proposed label, remove claims for "residual bacterial reduction." At this time, we are not considering bacterial reduction claims public health organisms. As an alternative, the following claim or variation on this claim would be acceptable: "Post-laundry additive with residual activity against *S. aureus* after 6 hours of contact and *K. pneumoniae* after 3 hours of contact"
- 2) On page 1 of the proposed label, revise the contact time for *Klebsiella pneumoniae* to 3 hours. A 3-log reduction was not achieved on the cotton and poly-cotton blend fabrics until 3 hours.
- 3) On page 2 of the proposed label, the directions for use should indicate that post-laundry residual activity against *S. aureus* and *K. pneumoniae* is applicable to properly/adequately stored, unused laundered fabrics/textiles. In addition, the directions for use section should include the contact times for the tested microorganisms.
- 4) Please include the ATCC numbers for the tested microorganisms (*K. pneumoniae* ATCC 4352 and *S. aureus* 6538) somewhere on the label. This may be down in text or by using a table format.
- 5) On pages 4 and 5, the optional marketing claims, please revise to read as follows:
 - a. Healthcare: As part of a diligent infection control program, experts recommend that a hospital should seek to reduce or eliminate exposure to pathogens to the greatest extent practical. One practical, inexpensive way to aid in this effort is to use *SilvaClean*® laundry additive. It provides residual post-laundry activity against *S. aureus* after 6 hours of contact and *K. pneumoniae* after 3 hours of contact when textiles such as bed linens and patient gowns are laundered through the SilvaClean program and properly stored. SilvaClean may be a helpful addition to an Infection Control program. SilvaClean is not a substitute for any existing component of a diligent Infection Control program. Practitioners should continue to implement fully all infection control measures.
 - b. Sports: As part of a diligent sports medicine infection control program, experts recommend that athletic programs should seek to reduce or eliminate exposure to pathogens to the greatest extent practical. One practical, inexpensive way to aid in this effort is to use *SilvaClean*® laundry additive. It provides residual post-laundry activity against *S. aureus* after 6 hours of contact and *K. pneumoniae* after 3 hours of contact when textiles such as bed linens and patient gowns are

laundered through the SilvaClean program and properly stored. SilvaClean may be a helpful addition to an Infection Control program. SilvaClean is not a substitute for any existing component of a diligent Infection Control program. Practitioners should continue to implement fully all infection control measures.



March 23, 2018

Via E-Mail and Hand Delivery

Ms. Aline Heffernan
U.S. Environmental Protection Agency
Office of Pesticide Programs (MC 4607M)
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Response to EPA Decision No. 536139 and PRIA Extension

Dear Ms. Heffernan:

Applied Silver, Inc. (ASI) is responding to the March 20, 2018, U.S. Environmental Protection Agency (EPA) 75-day letter (copy attached) regarding the pending registration amendment application for ASI's SilvaClean product, EPA Registration No. 90335-1.

In its letter, EPA states that ASI must respond by Monday, March 26, 2018, and agree to an extension of the current Pesticide Registration Improvement Extension Act (PRIA 3) deadline if it wishes for EPA's review of the pending application to continue under PRIA. That is ASI's intent, but as EPA's letter and accompanying March 7, 2018, efficacy review memorandum are devoid of a suitable explanation for its conclusion that the submitted data do not support the proposed claims, it is impossible for ASI to judge the extent of an extension that may be required to resolve the unspecified outstanding issues. As such, ASI requests a meeting with the Antimicrobials Division (AD) to discuss what the issues are, so that a path forward can be determined, and agrees to extend the current PRIA 3 date by 15 days, from April 9, 2018, until April 24, 2018. Ideally, ASI requests a meeting the week of March 26; alternatively, ASI requests a meeting the week of April 9.

ASI is stunned by the brevity of EPA's letter, and its noticeable lack of particularity. As you know, ASI has been meaningfully engaged with EPA since 2013 to develop its product in compliance with EPA's regulations. In the last year, ASI has engaged with AD multiple times regarding technical testing issues. ASI also presented a white paper to AD regarding its product development goals and met with Office Director Keigwin, then Division Director Knizner, and Deputy Division Director Weiss, and representatives from the Product Science and Regulatory Management branches on October 24, 2017, to discuss these goals and the path forward. ASI has appreciated AD's ongoing advice and the timeliness of responses during these efforts. In light of these communications, and the complete absence of

Ms. Aline Heffernan
March 23, 2018
Page 2

any reason to believe otherwise, ASI understood that its approach was reasonably on track. ASI is stunned and deeply disappointed with EPA's apparent rejection of its submission, and the carefully constructed basis on which it rests, in which EPA was engaged in creating. ASI is a small company. It is heavily invested in bringing a novel technology and business model to market to meet important and unmet societal health needs. A meeting with AD is needed urgently to clarify the path forward.

Of key concern, but certainly not exclusively, ASI notes that in the March 7, 2018, efficacy review memorandum, AD lists the documents that it reviewed. Noticeably absent is Volume 1 of the submission, Master Record Identification (MRID) No. 50440501. This Volume contains the October 24, 2017, meeting minutes, the white paper shared with AD before and discussed during that meeting, and a detailed discussion of the claims proposed in the amendment application. ASI requests that AD clarify whether the AD efficacy reviewers had access to that part of the submission before they concluded that all proposed claims should be denied.

As timing is urgent, Lynn Bergeson and Sheryl Dolan, The Acta Group, will follow up on this letter on ASI's behalf to discuss the meeting request.

Sincerely,



Sean D. Morham
Chief Executive Officer
Applied Silver, Inc.

Attachment

cc: Mr. Zeno Bain (w/attachment) (via e-mail and hand delivery)
Ms. Kathryn Montague (w/attachment) (via e-mail and hand delivery)
Mr. Steve Weiss (w/attachment) (via e-mail and hand delivery)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 20, 2018

Sheryl Dolan
Agent
Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Subject: Data Deficiency – Efficacy Review
Product Name: Silvaclean
EPA Registration Number: 90335-1
Application Date: 11/17/2017
Decision Number: 536139

Dear Ms. Dolan:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending July 23, 2018 to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are the data that was submitted does not support the proposed efficacy claims. Please see the attached efficacy review for more information.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on April 9, 2018. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than March 26, 2018 to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than March 26, 2018 that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by March 26, 2018, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

April 4th, 2018

Via E-mail

Kay Montague, Ph.D.
Acting Branch Chief, Regulatory Management Branch I
U.S. Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division (Mail code 7510P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: SilvaClean[®] Application

Dear Dr. Montague:

My name is Christopher Dawes and I serve as a healthcare industry advisor to Applied Silver. Until recently, I served as the Chief Executive Officer at the Lucile Packard Children's Hospital, a career that spanned 21 years. During this time, I have overseen major expansions of the facility including the recent move to a new facility dedicated pediatric care for children and mothers. I am proud of the culture of excellence in clinical services that we created, many of which are nationally ranked. I am writing to support a favorable review of the pending application with the U.S. Environmental Protection Agency (EPA) submitted by Applied Silver Inc. (ASI) to add public health claims to the labeling of its antimicrobial product, SilvaClean[®].

During my time as CEO of Lucile Packard, I have seen much progress over that time in reducing Hospital Acquired Infections (HAI) through programs that involve, among other things: improved patient care practices; more rigorous hygiene practices by medical and non-medical staff; and the systematic use of sterilizers, disinfectants, and sanitizers that are effective in reducing pathogen levels on objects and materials that will contact patients.

Despite better Infection Control programs, HAIs continue to be a constant challenge and serious problem for hospitals, nursing homes, and other medical care facilities. One of the most significant learnings in this field is the importance of properly using all available tools to control pathogens and to minimize the transmission of infections from patient to patient. Among other things, this means addressing all possible pathogen reservoirs and pathways by which patients might become infected. Currently, there are readily available tools to deal with pathogens possibly present on medical instruments and hard surfaces, but we lack cost-effective ways to deal with the potential for cross-contamination originating from pathogen loads in linens or other types of textiles (e.g., gowns, scrubs, hospital curtains, and related items). Controlling pathogens in these "soft" substrates could present real benefits for medical care.

I am familiar with and impressed by research conducted by Applied Silver in collaboration with Stanford University and published as "Reduction in bacterial contamination of

Kay Montague, Ph.D.
April 4, 2018
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hospital textiles by a novel silver-based laundry treatment," AJIC, 2016 Dec 1; 44(12):1705-1708. This study deployed linens -- some treated with SilvaClean and some without -- in a hospital and then measured the levels of different pathogens on the linens following patient use. The resulting data indicated that pathogen levels on hospital linens that had been treated with SilvaClean were significantly lower than the levels of these pathogens on linens without the treatment. While I cannot quantify how much HAI incidence would be impacted by reduced pathogen levels in hospital linens, I think that a product like SilvaClean could be shown to make a valuable difference.

To my knowledge, SilvaClean is the first product of its kind, and it appears to offer the promise of addressing pathogens in textile products in a unique and cost-effective way. SilvaClean is an efficient and economical technology that would fit easily into any hospital's routines. If it reduces pathogen levels, I expect it would be a valuable addition to Infection Control programs at any hospital.

Consequently, I encourage EPA to evaluate and approve this product in a timely manner, if you find that its use is safe for patients and it otherwise meets the Agency's requirements. Thank you.

Sincerely,



Christopher G. Dawes

cc: Ms. Anita Pease (via e-mail)
Mr. Zeno Bain (via e-mail)

April 4th, 2018

Via E-mail

Kay Montague, Ph.D.
Acting Branch Chief, Regulatory Management Branch I
U.S. Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division (Mail code 7510P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: SilvaClean[®] Application

Dear Dr. Montague:

My name is Sue Barnes and I serve as a clinical advisor to Applied Silver and previously was National Program Leader for Infection Prevention for Kaiser Permanente's 8 regions, 35+ hospitals and > 400 medical offices. I am board certified in Infection Control and Prevention and participated in the development of a number of APIC and AORN clinical guides to prevention of all types of healthcare associated infections. I am writing to support a favorable review of the pending application with the U.S. Environmental Protection Agency (EPA) submitted by Applied Silver Inc. (ASI) to add public health claims to the labeling of its antimicrobial product, SilvaClean[®].

I have worked in positions responsible for Infection Control programs for 29 years and have seen much progress over that time in reducing Healthcare Associated Infections (HAI) through programs that involve, among other things: improved patient care practices; more rigorous hand hygiene practices by medical and non-medical staff; strategies to reduce pathogen burden on patient skin; and the systematic use of sterilizers, disinfectants, sanitizers and cleaning products that are effective in reducing pathogen levels in the patient zone and on objects and materials that will contact patients.

Despite better Infection Control programs, HAIs continue to be a constant challenge and serious problem for hospitals, nursing homes, and other medical care facilities. One of the most significant learnings in this field is the importance of properly using all available tools to control pathogens and to minimize the transmission of infections from patient to patient. Among other things, this means addressing all possible pathogen reservoirs and pathways by which patients might become infected. Within the patient environment, there are readily available tools to deal with pathogens present on medical instruments and hard surfaces, but we lack cost-effective ways to deal with the potential for cross-contamination originating from pathogen loads in linens or other types of textiles (*e.g.*, gowns, scrubs, hospital curtains, and related items). Controlling pathogens in these "soft" substrates could present real benefits for medical care.

Kay Montague, Ph.D.
April 4, 2018
Page 2

I am familiar with and very encouraged by the research conducted by Stanford University using SilvaClean. "Reduction in bacterial contamination of hospital textiles by a novel silver-based laundry treatment," AJIC, 2016 Dec 1; 44(12):1705-1708. This study deployed linens -- some treated with SilvaClean and some without -- in a hospital and then measured the levels of different pathogens on the linens following patient use. The resulting data indicated that pathogen levels on hospital linens that had been treated with SilvaClean were significantly lower than the levels of these pathogens on linens without the treatment. While I cannot quantify how much HAI incidence would be impacted by reduced pathogen levels in hospital linens, I think that a product like SilvaClean could be shown to make a valuable difference.

To my knowledge, SilvaClean is the first product of its kind, and it appears to offer the promise of addressing pathogens in textile products in a unique and cost-effective way. SilvaClean is an efficient and economical technology that would fit easily into any hospital's routines. If it reduces pathogen levels, I expect it would be a valuable addition to any Infection Prevention and Control program.

Consequently, I encourage EPA to evaluate and approve this product in a timely manner, if you find that its use is safe for patients and it otherwise meets the Agency's requirements. Thank you.

Sincerely,



Sue Barnes, RN, CIC, FAPIC

cc: Ms. Anita Pease (via e-mail)
Mr. Zeno Bain (via e-mail)

April 5th, 2018

Via E-mail

Kay Montague, Ph.D.
Acting Branch Chief, Regulatory Management Branch I
U.S. Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division (Mail code 7510P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: SilvaClean[®] Application

Dear Dr. Montague:

My name is Dr. Ronald Loo and I am the Physician Co-Lead of the Health Innovations team at Kaiser Permanente. I have over thirty years of experience as a Kaiser Permanente urologist, was Regional Chief of Urology and currently serve as the Regional Assistant Medical Director of Performance Improvement. I am writing to support a favorable review of the pending application with the U.S. Environmental Protection Agency (EPA) submitted by Applied Silver Inc. (ASI) to add public health claims to the labeling of its antimicrobial product, SilvaClean[®].

I have spent many years evaluating new and innovative technologies for improved healthcare and patient experience. During this time, I have seen much progress over that time in reducing Hospital Acquired Infections (HAI) through programs that involve, among other things: improved patient care practices; more rigorous hygiene practices by medical and non-medical staff; and the systematic use of sterilizers, disinfectants, and sanitizers that are effective in reducing pathogen levels on objects and materials that will contact patients.

Despite better Infection Control programs, HAIs continue to be a constant challenge and serious problem for hospitals, nursing homes, and other medical care facilities. One of the most significant learnings in this field is the importance of properly using all available tools to control pathogens and to minimize the transmission of infections from patient to patient. Among other things, this means addressing all possible pathogen reservoirs and pathways by which patients might become infected. Currently, there are readily available tools to deal with pathogens possibly present on medical instruments and hard surfaces, but we lack cost-effective ways to deal with the potential for cross-contamination originating from pathogen loads in linens or other types of textiles (*e.g.*, gowns, scrubs, hospital curtains, and related items). Controlling pathogens in these “soft” substrates could present real benefits for medical care.

I am familiar and very encouraged by the research conducted by Stanford University using SilvaClean. "Reduction in bacterial contamination of hospital textiles by a novel silver-based laundry treatment," AJIC, 2016 Dec 1; 44(12):1705-1708. This study deployed linens -- some treated with SilvaClean and some without -- in a hospital and then measured the levels of different pathogens on the linens following patient use. The resulting data indicated that pathogen levels on hospital linens that had been treated with SilvaClean were significantly lower than the levels of these pathogens on linens without the treatment. While I cannot quantify how much HAI incidence would be impacted by reduced pathogen levels in hospital linens, I think that a product like SilvaClean could be shown to make a valuable difference.

To my knowledge, SilvaClean is the first product of its kind, and it appears to offer the promise of addressing pathogens in textile products in a unique and cost-effective way. SilvaClean is an efficient and economical technology that would fit easily into any hospital's routines. If it reduces pathogen levels, I expect it would be a valuable addition to an Infection Control program. I would hope other innovative hospitals would also adopt it.

Consequently, I encourage EPA to evaluate and approve this product in a timely manner, if you find that its use is safe for patients and it otherwise meets the Agency's requirements. Thank you.

Sincerely,



Ronald Loo, M.D.

cc: Ms. Anita Pease (via e-mail)
Mr. Zeno Bain (via e-mail)

David M. Joyner MD, LLC

Joyner Consulting Services
591 Cook Court, Hummelstown, Pa 17036
717-566-5839
dmjoyner70@aol.com

April 6, 2018

Via E-mail

Kay Montague, Ph.D.
Acting Branch Chief, Regulatory Management Branch I
U.S. Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division (Mail code 7510P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: SilvaClean® Application

Dear Dr. Montague:

My name is David Joyner, MD and I am a board-certified orthopedic surgeon with a sports medicine emphasis. I am an advisor to Applied Silver, Inc. I am writing to support a favorable review of the pending application with the U.S. Environmental Protection Agency (EPA) submitted by Applied Silver Inc. (ASI) to add public health claims to the labeling of its antimicrobial product, SilvaClean®.

I have worked in sports medicine and orthopedic surgery for 40 years and have seen much progress over that time in reducing Healthcare Associated Infections (HAI) through programs that involve, among other things: improved patient care practices; more rigorous hygiene practices by medical and non-medical staff; and the systematic use of sterilizers, disinfectants, and sanitizers that are effective in reducing pathogen levels on objects and materials that will contact patients.

Despite better Infection Control programs, HAIs continue to be a constant challenge and serious problem for hospitals, surgery centers and other medical care facilities. One of the most significant learnings in this field is the importance of properly using all available tools to control pathogens and to minimize the transmission of infections from patient to patient and from the environment to the patient. Among other things, this means addressing all possible pathogen reservoirs and pathways by which patients might become infected. Currently, there are readily available tools to deal with

pathogens possibly present on medical instruments and hard surfaces, but we lack cost-effective ways to deal with the potential for cross-contamination originating from pathogen loads in linens or other types of textiles (*e.g.*, gowns, scrubs, hospital curtains, and related items). Controlling pathogens in these “soft” substrates could present real benefits for medical care.

I am familiar with and very encouraged by the research conducted by Stanford University using SilvaClean. “Reduction in bacterial contamination of hospital textiles by a novel silver-based laundry treatment,” *AJIC*, 2016 Dec 1; 44(12):1705-1708. This study deployed linens – some treated with SilvaClean and some without -- in a hospital and then measured the levels of different pathogens on the linens following patient use. The resulting data indicated that pathogen levels on hospital linens that had been treated with SilvaClean were significantly lower than the levels of these pathogens on linens without the treatment. I think that a product like SilvaClean could be shown to make a valuable difference.

To my knowledge, SilvaClean is the first product of its kind, and it appears to offer the promise of addressing pathogens in textile products in a unique and very cost-effective way. SilvaClean is an efficient and economical technology that would fit easily into any hospital and surgery center’s routines. If it reduces pathogen levels, I expect it would be a valuable addition to any Infection Control program.

Consequently, I encourage EPA to evaluate and approve this product in a timely manner, if you find that its use is safe for patients and it otherwise meets the Agency’s requirements. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Joyner", with a stylized, flowing script.

David Joyner, MD, FACS

cc: Ms. Anita Pease (via e-mail)
Mr. Zeno Bain (via e-mail)

April 10, 2018

Via E-mail

Kay Montague, Ph.D.
Acting Branch Chief, Regulatory Management Branch I
U.S. Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division (Mail code 7510P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: SilvaClean® Application

Dear Dr. Montague:

My name is Aydin Nazmi and I am an epidemiologist serving as Associate Professor at California Polytechnic State University, San Luis Obispo. I am writing to support a favorable review of the pending application with the U.S. Environmental Protection Agency (EPA) submitted by Applied Silver Inc. (ASI) to add public health claims to the labeling of its antimicrobial product, SilvaClean®.

I have worked as a professor of public health and also nutrition for a decade and have seen much progress over that time in reducing Hospital Acquired Infections (HAI) through programs that involve, among other things: improved patient care practices; more rigorous hygiene practices by medical and non-medical staff; and the systematic use of sterilizers, disinfectants, and sanitizers that are effective in reducing pathogen levels on objects and materials that will contact patients.

Despite better Infection Control programs, HAIs continue to be a constant challenge and serious problem for medical facilities and athletic programs. One of the most significant learnings in this field is the importance of properly using all available tools to control pathogens and to minimize the transmission of infections between individuals. Among other things, this means addressing all possible pathogen reservoirs and pathways by which patients might become infected. Currently, there are readily available tools to deal with pathogens possibly present on medical instruments and hard surfaces, but we lack cost-effective ways to deal with the potential for cross-contamination originating from pathogen loads in linens or other types of

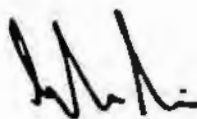
textiles (e.g., gowns, scrubs, hospital curtains, and related items). Controlling pathogens in these "soft" substrates could present real benefits for medical care.

I was a co-author of the research conducted by Stanford University using SilvaClean. "Reduction in bacterial contamination of hospital textiles by a novel silver-based laundry treatment," AJIC, 2016 Dec 1; 44(12):1705-1708. This study deployed linens -- some treated with SilvaClean and some without -- in a hospital and then measured the levels of different pathogens on the linens following patient use. The resulting data indicated that pathogen levels on hospital linens that had been treated with SilvaClean were significantly lower than the levels of these pathogens on linens without the treatment. While I cannot quantify how much HAI incidence would be impacted by reduced pathogen levels in hospital linens, I think that a product like SilvaClean could be shown to make a valuable difference.

To my knowledge, SilvaClean is the first product of its kind, and it appears to offer the promise of addressing pathogens in textile products in a unique and cost-effective way. SilvaClean is an efficient and economical technology that would fit easily into any hospital's routines. If it reduces pathogen levels, I expect it would be a valuable addition to my Infection Control program. In addition, SilvaClean is beneficial to athletic programs of all levels. California Polytechnic State University in San Luis Obispo is a customer of the company that is currently using the product as part of their infection prevention programs.

Consequently, I encourage EPA to evaluate and approve this product in a timely manner, if you find that its use is safe for patients and it otherwise meets the Agency's requirements. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read 'A. Nazmi'.

Aydin Nazmi, PhD

cc: Ms. Anita Pease (via e-mail)
Mr. Zeno Bain (via e-mail)

April 9, 2018

Via E-mail

Kay Montague, Ph.D.
Acting Branch Chief, Regulatory Management Branch I
U.S. Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division (Mail code 7510P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: SilvaClean[®] Application

Dear Dr. Montague:

My name is Dr. Jethro Trees Ritter and I am a board certified physician specializing in Infectious Diseases and Internal Medicine. I am the managing partner of Central Coast Infectious Diseases Consultants where I assist other physicians daily with challenging and complicated cases of patient infection. I am a customer of and an advisor to Applied Silver. Additionally, I am the Medical Director of the Infection Control Programs for five California Central Coast Hospitals (Sierra Vista Medical Center, Twin Cities Medical Center, Marian Medical Center, Arroyo Grande Community Hospital, and French Hospital Medical Center). I am trained and certified as a Hospital Epidemiologist by the CDC and the Society for Healthcare Epidemiology of America. I am writing to support a favorable review of the pending application with the U.S. Environmental Protection Agency (EPA) submitted by Applied Silver Inc. (ASI) to add public health claims to the labeling of its antimicrobial product, SilvaClean[®].

I have worked in positions responsible for Infection Control programs for 12 years and have seen much progress over that time in reducing Hospital Acquired Infections (HAI) through programs that involve, among other things: improved patient care practices, more rigorous hygiene practices by medical and non-medical staff, and the systematic use of sterilizers, disinfectants, and sanitizers that are effective in reducing pathogen levels on objects and materials that will contact patients.

Despite better Infection Control programs, HAIs continue to be a constant challenge and serious problem for hospitals, nursing homes, and other medical care facilities. One of the most significant learnings in this field is the importance of properly using all available tools to control pathogens and to minimize the transmission of infections from patient to patient. Among other things, this means addressing all possible pathogen reservoirs and pathways by which patients might become infected. Currently, there are readily available tools to deal with pathogens possibly present on medical instruments and hard surfaces, but we lack cost-effective ways to deal with the potential for cross-contamination originating from pathogen loads in linens

Kay Montague, Ph.D.
April 4th, 2018
Page 2

or other types of textiles (e.g., gowns, scrubs, hospital curtains, and related items). Controlling pathogens in these "soft" substrates could present real benefits for medical care.

I am familiar with and very encouraged by the research conducted by Stanford University using SilvaClean. "Reduction in bacterial contamination of hospital textiles by a novel silver-based laundry treatment," AJIC, 2016 Dec 1; 44(12):1705-1708. This study deployed linens -- some treated with SilvaClean and some without -- in a hospital and then measured the levels of different pathogens on the linens following patient use. The resulting data indicated that pathogen levels on hospital linens that had been treated with SilvaClean were significantly lower than the levels of these pathogens on linens without the treatment. While I cannot quantify how much HAI incidence would be impacted by reduced pathogen levels in hospital linens, I think that a product like SilvaClean could be shown to make a valuable difference.

To my knowledge, SilvaClean is the first product of its kind, and it appears to offer the promise of addressing pathogens in textile products in a unique and cost-effective way. SilvaClean is an efficient and economical technology that would fit easily into any hospital's routines. If it reduces pathogen levels, I expect it would be a valuable addition to my Infection Control program. I would hope other Infection Control professionals would also adopt it.

Consequently, I encourage EPA to evaluate and approve this product in a timely manner, if you find that its use is safe for patients and it otherwise meets the Agency's requirements. Thank you.

Sincerely,



J. Trees Ritter, DO, FIDSA

cc: Ms. Anita Pease (via e-mail)
Mr. Zeno Bain (via e-mail)



March 23, 2018

Via E-Mail and Hand Delivery

Ms. Aline Heffernan
U.S. Environmental Protection Agency
Office of Pesticide Programs (MC 4607M)
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Response to EPA Decision No. 536139 and PRIA Extension

Dear Ms. Heffernan:

Applied Silver, Inc. (ASI) is responding to the March 20, 2018, U.S. Environmental Protection Agency (EPA) 75-day letter (copy attached) regarding the pending registration amendment application for ASI's SilvaClean product, EPA Registration No. 90335-1.

In its letter, EPA states that ASI must respond by Monday, March 26, 2018, and agree to an extension of the current Pesticide Registration Improvement Extension Act (PRIA 3) deadline if it wishes for EPA's review of the pending application to continue under PRIA. That is ASI's intent, but as EPA's letter and accompanying March 7, 2018, efficacy review memorandum are devoid of a suitable explanation for its conclusion that the submitted data do not support the proposed claims, it is impossible for ASI to judge the extent of an extension that may be required to resolve the unspecified outstanding issues. As such, ASI requests a meeting with the Antimicrobials Division (AD) to discuss what the issues are, so that a path forward can be determined, and agrees to extend the current PRIA 3 date by 15 days, from April 9, 2018, until April 24, 2018. Ideally, ASI requests a meeting the week of March 26; alternatively, ASI requests a meeting the week of April 9.

ASI is stunned by the brevity of EPA's letter, and its noticeable lack of particularity. As you know, ASI has been meaningfully engaged with EPA since 2013 to develop its product in compliance with EPA's regulations. In the last year, ASI has engaged with AD multiple times regarding technical testing issues. ASI also presented a white paper to AD regarding its product development goals and met with Office Director Keigwin, then Division Director Knizner, and Deputy Division Director Weiss, and representatives from the Product Science and Regulatory Management branches on October 24, 2017, to discuss these goals and the path forward. ASI has appreciated AD's ongoing advice and the timeliness of responses during these efforts. In light of these communications, and the complete absence of

Ms. Aline Heffernan
March 23, 2018
Page 2

any reason to believe otherwise, ASI understood that its approach was reasonably on track. ASI is stunned and deeply disappointed with EPA's apparent rejection of its submission, and the carefully constructed basis on which it rests, in which EPA was engaged in creating. ASI is a small company. It is heavily invested in bringing a novel technology and business model to market to meet important and unmet societal health needs. A meeting with AD is needed urgently to clarify the path forward.

Of key concern, but certainly not exclusively, ASI notes that in the March 7, 2018, efficacy review memorandum, AD lists the documents that it reviewed. Noticeably absent is Volume 1 of the submission, Master Record Identification (MRID) No. 50440501. This Volume contains the October 24, 2017, meeting minutes, the white paper shared with AD before and discussed during that meeting, and a detailed discussion of the claims proposed in the amendment application. ASI requests that AD clarify whether the AD efficacy reviewers had access to that part of the submission before they concluded that all proposed claims should be denied.

As timing is urgent, Lynn Bergeson and Sheryl Dolan, The Acta Group, will follow up on this letter on ASI's behalf to discuss the meeting request.

Sincerely,



Sean D. Morham
Chief Executive Officer
Applied Silver, Inc.

Attachment

cc: Mr. Zeno Bain (w/attachment) (via e-mail and hand delivery)
Ms. Kathryn Montague (w/attachment) (via e-mail and hand delivery)
Mr. Steve Weiss (w/attachment) (via e-mail and hand delivery)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 20, 2018

Sheryl Dolan
Agent
Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Subject: Data Deficiency – Efficacy Review
Product Name: Silvaclean
EPA Registration Number: 90335-1
Application Date: 11/17/2017
Decision Number: 536139

Dear Ms. Dolan:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending July 23, 2018 to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are the data that was submitted does not support the proposed efficacy claims. Please see the attached efficacy review for more information.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on April 9, 2018. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than March 26, 2018 to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than March 26, 2018 that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by March 26, 2018, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Page 3 of 3
EPA Reg. No. 90355-1
Decision No. 536139

Please respond to this letter by 03/26/2018. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at heffernan.aline@epa.gov.

Sincerely,



Zeno Bain, Product Manager 33
Regulatory Management Branch
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Efficacy Review



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON,
DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

March 07, 2018

MEMORANDUM

Subject: Efficacy Review for SilvaClean, EPA Reg. No. 90335-1; DP Barcode: D444670; Submission #: 1012169; E-Sub # 24426.

From: Ibrahim Laniyan, Ph.D.
Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Ph.D.
Acting Efficacy Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Zeno Bain, PM33 / Aline Heffernan
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Formulation from the Label:

Active Ingredients	% by wt.
Silver	22.5 %
Other Ingredients:	77.5 %
Total	100.0 %

I. BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment

Currently registered efficacy claim(s): application to textiles after each laundering to protect fibers against stain- and odor-causing bacteria, mold, and mildew.

Requested action(s): Add residual self-sanitizing laundry additive claim

Documents considered in this review:

- Letter from applicant to EPA dated November 17, 2017
- Application for Pesticide (EPA form 8570-1) dated November 17, 2017
- Certification with Respect to Citation of 1ata (EPA Form 8570-34) dated November 17, 2017
- Data Matrix (EPA Form 8570-35) dated November 17, 2017
- 7 efficacy studies (MRID 504405-01-504405-08)
- 1 additional MRID dated 01/23/2018 with supplemental information to address the technical screen (MRID 50504501)
- Proposed label dated November 17, 2017

II. PROPOSED DIRECTIONS FOR USE

For ongoing residual self-sanitizing activity against *Klebsiella pneumoniae*, and *Staphylococcus aureus*, on cotton, cotton/polyester blends, and microfiber fabrics and for preservation against stain- and odor causing bacteria, mold and mildew use as directed.

SilvaClean® is a concentrate that must be diluted with distilled or deionized water before use.

Ongoing residual self-sanitizing: Dilute the following volumes of SilvaClean® concentrate volumes per 100 lbs of selected fabric type into 500 or 1000 mL distilled or deionized water and dose as part of the final rinse step in the laundry process to achieve residual self-sanitization:

- 0.024 oz per 100 lbs cotton
- 0.032 oz per 100 lbs cotton/poly blend
- 0.048 oz per 100 lbs microfiber

Add the diluted solution into the final rinse cycle of a laundry process. Allow to soak with fabric at least 2 minutes.

III. STUDY SUMMARIES

1. MRID 504405-02 “Treating Fabric with Self-Sanitizing Laundry Test Solution” for Test Solution, by Sean Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1777.

This study was conducted to treat three fabric types, Microfiber (100% Polyester, lot: 286-E), Cotton (100%, lot: 286-A), and Cotton/Poly Blend (55% Cotton, 45% Polyester, lot: 286-B), with “Test Solution” (lots: 170821-1, 170821-2, and 170821-3) during laundry, according to Microchem Laboratory protocol P1937 (copy provided). The product, adjusted to the LCL concentration, was diluted to 0.0000310 ration in 200ppm hard tap

water for polyester, 0.0000155 for cotton, and 0.0000207 for blend. Product was applied during 23-minute rinse cycle with 2-minute soaking time; and 55-minute drying time.

Treated fabrics were assigned the following lot numbers:

Treated Microfiber Fabric: M-1-11SEP2017A, M-2-11SEP2017A, and M-3-11SEP2017A

Treated Cotton Fabric: C-1-12SEP2017A, C-2-12SEP2017A, and C-3-12SEP2017A

Treated Cotton/Poly Blend Fabric: CP-1-12SEP2017A, CP-2-12SEP2017A, and CP-3-12SEP2017A

2. MRID 504405-03 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *S. aureus*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1810.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (C-1-12SEP2017A, C-2-12SEP2017A, and C-3-12SEP2017A) of "Treated Cotton Fabric", were tested according to Microchem Protocol P1938 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

3. MRID 504405-04 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *S. aureus*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1813.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (CP-1-12SEP2017A, CP-2-12SEP2017A, and CP-3-12SEP2017A) of "Treated Cotton/Poly Blend Fabric", were tested according to Microchem Protocol PP1994 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, 24 hours, 48 hours, and 72 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

4. MRID 504405-05 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *S. aureus*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1814.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (M-1-11SEP2017A, M-2-11SEP2017A, and M-3-11SEP2017A) of "Treated Microfiber Fabric", were tested according to Microchem Protocol P2005 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

5. MRID 504405-06 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *K. pneumoniae*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1811.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Three lots (C-1-12SEP2017A, C-2-12SEP2017A, and C-3-12SEP2017A) of "Treated Cotton Fabric", were tested according to Microchem Protocol P1979 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24

hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36 \pm 1^\circ\text{C}$.

6. MRID 504405-07 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *K. pneumoniae*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1812.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Three lots (CP-1-12SEP2017A, CP-2-12SEP2017A, and CP-3-12SEP2017A) of "Treated Cotton/Poly Blend Fabric", were tested according to Microchem Protocol PP1993 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36 \pm 1^\circ\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, 24 hours, 48 hours, and 72 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36 \pm 1^\circ\text{C}$.

7. MRID 504405-08 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *K. pneumoniae*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1815.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Three lots (M-1-11SEP2017A, M-2-11SEP2017A, and M-3-11SEP2017A) of "Treated Microfiber Fabric", were tested according to Microchem Protocol P2006 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36 \pm 1^\circ\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36 \pm 1^\circ\text{C}$.

V. RESULTS

MRID	Organism	Lot #	Controls	% Reduction							
				30 min.	1 hr.	2 hrs.	3 hrs.	6 hrs.	24 hrs.	48 hrs.	72 hrs.
Treated Cotton Fabrics											
50440 5-03	Staphylococcus aureus (ATCC 6538)	C-1-12SEP2017A	3.6 x 10 ⁵ 1.03 x 10 ⁶	56.09	89.43	98.22	99.86	>99.99	>99.99	-	-
		C-2-12SEP2017A		65.90	75.99	99.16	99.54	>99.9	>99.99	-	-
		C-3-12SEP2017A		57.66	90.60	98.49	>99.9	>99.9	>99.99	-	-
50440 5-06	Klebsiella pneumoniae (ATCC 4352)	C-1-12SEP2017A	5.25 x 10 ⁵ 1.09 x 10 ⁶	32.56	38.61	99.77	>99.9 9	>99.99 99	>99.99 999	-	-
		C-2-12SEP2017A		32.09	69.24	99.68	>99.9 9	>99.99 9	>99.99 999	-	-
		C-3-12SEP2017A		0	45.32	99.68	>99.9 9	>99.99 99	>99.99 999	-	-
Treated Microfiber Fabrics											
50440 5-05		M-1-11SEP2017A	4.5 x 10 ⁵	61.36	95.83	99.70	>99.9	>99.9	-	-	-

MRID	Organism	Lot #	Controls	% Reduction							
				30 min.	1 hr.	2 hrs.	3 hrs.	6 hrs.	24 hrs.	48 hrs.	72 hrs.
	<i>Staphylococcus aureus</i> (ATCC 6538)	M-2-11SEP2017A	4.33 x 10 ⁵	41.59	97.45	99.56	99.51	>99.9	-	-	-
		M-3-11SEP2017A		72.04	91.79	99.49	>99.9	>99.9	-	-	-
50440 5-08	<i>Klebsiella pneumoniae</i> (ATCC 4352)	M-1-11SEP2017A	3.58 x 10 ⁵	24.70	98.14	>99.9	>99.9	>99.99	>99.99	-	-
		M-2-11SEP2017A	1.79 x 10 ⁵	54.65	97.23	>99.9	>99.9	>99.99	>99.99	-	-
		M-3-11SEP2017A	10 ⁵	86.04	99.77	>99.9	>99.9	>99.99	>99.99	-	-
Treated Cotton/Poly Blend Fabrics											
50440 5-04	<i>Staphylococcus aureus</i> (ATCC 6538)	CP-1-12SEP2017A	5.89 x 10 ⁵	46.29	65.06	95.07	99.03	>99.99	>99.99	>99.9999	>99.9999
		CP-2-12SEP2017A	6.71 x 10 ⁵	53.33	98.44	99.87	99.18	>99.99	>99.99	>99.9999	>99.9999
		CP-3-12SEP2017A	10 ⁵	35.05	70.17	99.82	99.55	99.99	>99.99	>99.9999	>99.9999
50440 5-07	<i>Klebsiella pneumoniae</i> (ATCC 4352)	CP-1-12SEP2017A	1.57 x 10 ⁶	40.10	66.92	99.88	>99.99	>99.99	>99.99	>99.9999	>99.9999
		CP-2-12SEP2017A	1.04 x 10 ⁶	37.87	96.39	>99.99	>99.99	>99.99	>99.99	>99.9999	>99.9999
		CP-3-12SEP2017A	10 ⁶	50.25	92.48	>99.9	>99.99	>99.99	>99.99	>99.9999	>99.9999

VI. CONCLUSIONS

MRID #	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support label claims?
504405-02 - 504405-08	Residual Bacterial Reduction for Post Laundry Contaminations	Laundered Dried Fabrics/Textiles	0.0000310 ration for polyester, 0.0000155 for cotton, and 0.0000207 for blend.	23-minute rinse cycle with 2-minute soaking time; and 55-minute drying time	No	200ppm hard tap water	<ul style="list-style-type: none"> <i>Staphylococcus aureus</i> (ATCC 6538) <i>Klebsiella pneumoniae</i> (ATCC 4352) 	No

VII. LABEL

Proposed Label dated November 17, 2017

1. The proposed label claims that the product, SilvaClean (EPA Reg. No. 90335-1), provides ongoing residual self-sanitizing activity against *Staphylococcus aureus* and *Klebsiella pneumoniae* on cotton, cotton/polyester blend and microfiber materials until the next laundering event. **These claims are not acceptable as they are not supported by the submitted data.**

All claims for residual self-sanitizing activity should be removed. The following provide rationale as to why these claims are not acceptable:

- To make label claims as a "Sanitizer" a product should demonstrate a 3-log reduction at a contact time ≤ 5 minutes.
 - o A 3-log reduction was not achieved for any of the fabric types at a 30-minute contact time
- Claims for "ongoing" are synonymous with continuous and testing to support these claims should include re-inoculation steps.

2. The applicant must make the following changes to the proposed label, as appropriate:

- Remove all claims and associated directions for use as a "residual self-sanitizer"
- Remove all claims for "self-sanitizing" and any mention of specific microorganisms (e.g. *Staphylococcus aureus* and *Klebsiella pneumoniae*).
- Remove the optional marketing claims for healthcare and sports

Applied Silver + Hort. - Minnesota
 April 12, 2013 video link

Name	Affiliation	Contact
Dr. Jeff Exler	The Acta Group	360.441.0000
William Jordan	consultant to ASD	202.206.5031
[Steven Weiss	EPA/OP/AD	703.509.8043
Emily Mitchell	EPA/OP/AD	703-308-8583
Kristen Willis	EPA/OP/AD	703-347-5115
Zeno Bain	EPA/OP/AD	703-347-5115
Anita Reese	EPA/OP/AD	703-305-0392
Sean Marham	Applied Silver	707-363-4139
Lynne Lange	Applied Silver	202-517-5081

AGENDA

**Applied Silver, Inc.
U.S. Environmental Protection Agency**

MEETING

**April 12, 2018
11:00 a.m. (EDT)
Arlington, VA**

- 1.0 Welcome and Introductions (2 minutes)
- 2.0 Presentation (15 minutes)
 - 2.1 Overview of SilvaClean[®] and Pending Registration Amendment
 - 2.2 Summary of Supplemental Information from Public Health Industry Leaders
 - 2.3 Claims Supported by Extant Data
- 3.0 Discussion (40 minutes)
- 4.0 Next Steps (3 minutes)
- 5.0 Adjourn

Placentia-Linda

HOSPITAL

April 4, 2018

Kay Montague, Ph.D.
Acting Branch Chief, Regulatory Management Branch I
U.S. Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division (Mail code 7510P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: SilvaClean® Application

Dear Dr. Montague:

My name is Valerie Laktash, and I serve as Director of Facility Services for Placentia-Linda Hospital. I am writing to support a favorable review of the pending application with the U.S. Environmental Protection Agency (EPA) submitted by Applied Silver Inc. (ASI) to add public health claims to the labeling of its antimicrobial product, SilvaClean®.

I have worked in positions responsible for patient satisfaction and facility services for 16 years and have seen much progress over that time in reducing Healthcare Associated Infections (HAI) through programs that involve, among other things: improved patient care practices; more rigorous hygiene practices by medical and non-medical staff; and the systematic use of sterilizers, disinfectants, and sanitizers that are effective in reducing pathogen levels on objects and materials that will contact patients.

Despite better Infection Control programs, HAIs continue to be a constant challenge and serious problem for hospitals, and other medical care facilities. One of the most significant learnings in this field is the importance of properly using all available tools to control pathogens and to minimize the transmission of infections from patient to patient. Among other things, this means addressing all possible pathogen reservoirs and pathways by which patients might become infected. Currently, there are readily available tools to deal with pathogens possibly present on medical instruments and hard surfaces, but we lack cost-effective ways to deal with the potential for cross-contamination originating from pathogen loads in linens or other types of textiles (e.g., gowns, scrubs, hospital curtains, and related items). Controlling pathogens in these "soft" substrates could present real benefits for medical care.

I am familiar with and very encouraged by the research conducted by Stanford University using SilvaClean. "Reduction in bacterial contamination of hospital textiles by a novel silver-based laundry treatment," AJIC, 2016 Dec 1; 44(12):1705-1708. This study deployed linens – some treated with SilvaClean and some without – in a hospital, and then measured the levels of different pathogens on the linens following patient use. The resulting data indicated that pathogen levels on hospital linens that had been treated with SilvaClean were significantly lower than the levels of these pathogens on linens without the treatment. I think that a product like SilvaClean could be shown to make a valuable difference.

To my knowledge, SilvaClean is the first product of its kind, and it appears to offer the promise of addressing pathogens in textile products in a unique and very cost-effective way. SilvaClean is an efficient and economical technology that would fit easily into any hospital's routines. If it reduces pathogen levels, I expect it would be a valuable addition to my Infection Control program. I would hope other Infection Control professionals would also adopt it.

Consequently, I encourage EPA to evaluate and approve this product in a timely manner, if you find that its use is safe for patients and it otherwise meets the Agency's requirements. Thank you.

Sincerely,



Valerie Laktash, MBA, CHFM, CLSS-HC, CEPSS-HC

cc: Ms. Anita Pease (via e-mail)
Mr. Zenn Bain (via e-mail)

Placentia-Linda Hospital
1301 N. Rose Drive, Placentia, CA 92870

April 4, 2018Via E-mail

Kay Montague, Ph.D.
Acting Branch Chief, Regulatory Management Branch I
U.S. Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division (Mail code 7510P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: SilvaClean® Application

Dear Dr. Montague:

My name is Dr. Leopold Selker and I serve as a Research Scholar in Residence at Cal Poly. I am writing today to support a favorable review of the pending application with the U.S. Environmental Protection Agency (EPA) submitted by Applied Silver Inc. (ASI) to add public health claims to the labeling of its antimicrobial product, SilvaClean®. As former President of the NorthShore University Health System Research Institute and a former Scholar in Residence at the Institute of Medicine-National Academy of Sciences, I feel very comfortable commenting on this application.

I have worked in positions responsible for oversight of Infection Control research for 16 years and have seen much progress over that time in reducing Hospital Acquired Infections (HAI) through programs that involve, among other things: improved patient care practices; more rigorous hygiene practices by medical and non-medical staff; and the systematic use of sterilizers, disinfectants, and sanitizers that are effective in reducing pathogen levels on objects and materials that will contact patients.

Despite better Infection Control programs, HAIs continue to be a constant challenge and serious problem for hospitals, nursing homes, and other medical care facilities. One of the most significant learnings in this field is the importance of properly using all available tools to control pathogens and to minimize the transmission of infections from patient to patient. Among other things, this means addressing all possible pathogen reservoirs and pathways by which patients might become infected. Currently, there are readily available tools to deal with pathogens possibly present on medical instruments and hard surfaces, but we lack cost-effective ways to deal with the potential for cross-contamination originating from pathogen loads in linens

or other types of textiles (e.g., gowns, scrubs, hospital curtains, and related items). Controlling pathogens in these “soft” substrates could present real benefits for medical care.

I am familiar with and encouraged by the research conducted by Stanford University using SilvaClean. “Reduction in bacterial contamination of hospital textiles by a novel silver-based laundry treatment,” AJIC, 2016 Dec 1; 44(12):1705-1708. This study deployed linens -- some treated with SilvaClean and some without -- in a hospital and then measured the levels of different pathogens on the linens following patient use. The resulting data indicated that pathogen levels on hospital linens that had been treated with SilvaClean were significantly lower than the levels of these pathogens on linens without the treatment. While I cannot quantify how much HAI incidence would be impacted by reduced pathogen levels in hospital linens, I think that a product like SilvaClean could be shown to make a valuable difference.

To my knowledge, SilvaClean is the first product of its kind, and it appears to offer the promise of addressing pathogens in textile products in a unique and cost-effective way. SilvaClean is an efficient and economical technology that would fit easily into any hospital’s routines. If it reduces pathogen levels, I expect it would be a valuable addition to any Infection Control program. Based upon the research record to date, I would expect Infection Control professionals to support its widespread adoption.

Consequently, I encourage EPA to evaluate and approve this product with all possible dispatch, if you also find that its use is safe for patients and it otherwise meets the Agency’s requirements. Thank you.

Sincerely,

Leopold Selker

Leopold G. Selker, Ph.D., MBA
Research Scholar in Residence
Cal Poly
San Luis Obispo, CA 93407
Tele: 805-254-0206
lselker@calpoly.edu

cc: Ms. Anita Pease (via e-mail)
Mr. Zeno Bain (via e-mail)

April 4th, 2018

Via E-mail

Kay Montague, Ph.D.
Acting Branch Chief, Regulatory Management Branch I
U.S. Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division (Mail code 7510P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: SilvaClean[®] Application

Dear Dr. Montague:

My name is Dr. John Openshaw and I am an infectious disease physician in the Department of Medicine at Stanford University. The primary areas of my research focus have been hospital epidemiology and global health.

In this capacity, I am also a faculty fellow at the Center for Innovation in Global Health at the Stanford University School of Medicine. I also practice clinical infectious diseases at Stanford Hospital, the Palo Alto Veterans Affairs Hospital, and San Mateo Medical Center.

I am writing to support a favorable review of the pending application with the U.S. Environmental Protection Agency (EPA) submitted by Applied Silver Inc. (ASI) to add public health claims to the labeling of its antimicrobial product, SilvaClean[®].

As an infectious disease physician, I have seen progress in reducing Hospital Acquired Infections (HAI) through programs that involve more rigorous hygiene practices by medical and non-medical staff and the systematic use of sterilizers, disinfectants, and sanitizers that are effective in reducing pathogen burden on objects and materials that will contact patients.

Despite better Infection Control programs, HAIs continue to be a challenge and serious problem for hospitals, nursing homes, and other medical care facilities.

To combat this challenge, we must use all available tools to control pathogens in healthcare settings. This means addressing key pathogen reservoirs and pathways by which patients might become infected. Currently, there are readily available tools to deal with pathogens present on medical instruments and hard surfaces, but we lack good ways to deal with the potential pathogen loads on linens and other types of textiles (e.g., gowns, scrubs, and hospital curtains).

I collaborated with Applied Silver on research conducted using SilvaClean. The results of this research, which I was involved in authoring, were published in the American Journal of Infection Control and also presented at The Society of Healthcare Epidemiology of America conference (see here for publication: "Reduction in bacterial contamination of hospital textiles by a novel silver-based laundry treatment," AJIC, 2016 Dec 1; 44(12):1705-1708).

Our study deployed linens -- some treated with SilvaClean and some without -- in several hospitals and then measured the levels of pathogens on the linens following patient use. The analysis indicated that pathogen burdens on hospital linens that had been treated with SilvaClean were significantly lower than the levels of these pathogens on linens without the treatment.

While I cannot quantify how much HAI incidence would be impacted by reduced pathogen levels in hospital linens, I think that a product like SilvaClean could be shown to make a valuable difference.

To my knowledge, SilvaClean is the first product of its kind, and it appears to offer the promise of addressing pathogens in textile products in a unique way. SilvaClean is an efficient technology that would fit easily into many hospitals' routines. If it reduces pathogen levels and this reduction leads to fewer HAIs, I expect it would be a valuable addition to hospital infection control programs.

Consequently, I encourage EPA to evaluate and approve this product in a timely manner if you find that its use is safe for patients and it otherwise meets the Agency's requirements.

Sincerely,



John Openshaw, M.D.

cc: Ms. Anita Pease (via e-mail)
Mr. Zeno Bain (via e-mail)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON,
DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

March 07, 2018

MEMORANDUM

Subject: Efficacy Review for SilvaClean, EPA Reg. No. 90335-1; DP Barcode: D444670; Submission #: 1012169; E-Sub # 24426.

From: Ibrahim Laniyan, Ph.D.
Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Ph.D.
Acting Efficacy Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Zeno Bain, PM33 / Aline Heffernan
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Formulation from the Label:

Active Ingredients	% by wt.
Silver	22.5 %
Other Ingredients:	77.5 %
Total	100.0 %

I. BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment

Currently registered efficacy claim(s): application to textiles after each laundering to protect fibers against stain- and odor-causing bacteria, mold, and mildew.

Requested action(s): Add residual self-sanitizing laundry additive claim

Documents considered in this review:

- Letter from applicant to EPA dated November 17, 2017
- Application for Pesticide (EPA form 8570-1) dated November 17, 2017
- Certification with Respect to Citation of 1ata (EPA Form 8570-34) dated November 17, 2017
- Data Matrix (EPA Form 8570-35) dated November 17, 2017
- 7 efficacy studies (MRID 504405-02-504405-08)
- 1 additional MRID dated 01/23/2018 with supplemental information to address the technical screen (MRID 550504501)
- Proposed label dated November 17, 2017

II. PROPOSED DIRECTIONS FOR USE

For ongoing residual self-sanitizing activity against *Klebsiella pneumoniae*, and *Staphylococcus aureus*, on cotton, cotton/polyester blends, and microfiber fabrics and for preservation against stain- and odor causing bacteria, mold and mildew use as directed.

SilvaClean® is a concentrate that must be diluted with distilled or deionized water before use.

Ongoing residual self-sanitizing: Dilute the following volumes of SilvaClean® concentrate volumes per 100 lbs of selected fabric type into 500 or 1000 mL distilled or deionized water and dose as part of the final rinse step in the laundry process to achieve residual self-sanitization:

- 0.024 oz per 100 lbs cotton
- 0.032 oz per 100 lbs cotton/poly blend
- 0.048 oz per 100 lbs microfiber

Add the diluted solution into the final rinse cycle of a laundry process. Allow to soak with fabric at least 2 minutes.

III. STUDY SUMMARIES

1. MRID 504405-02 "Treating Fabric with Self-Sanitizing Laundry Test Solution" for Test Solution, by Sean Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1777.

This study was conducted to treat three fabric types, Microfiber (100% Polyester, lot: 286-E), Cotton (100%, lot: 286-A), and Cotton/Poly Blend (55% Cotton, 45% Polyester, lot: 286-B), with "Test Solution" (lots: 170821-1, 170821-2, and 170821-3) during laundry, according to Microchem Laboratory protocol P1937 (copy provided). The product, adjusted to the LCL concentration, was diluted to 0.0000310 ration in 200ppm hard tap

water for polyester, 0.0000155 for cotton, and 0.0000207 for blend. Product was applied during 23-minute rinse cycle with 2-minute soaking time; and 55-minute drying time.

Treated fabrics were assigned the following lot numbers:

Treated Microfiber Fabric: M-1-11SEP2017A, M-2-11SEP2017A, and M-3-11SEP2017A

Treated Cotton Fabric: C-1-12SEP2017A, C-2-12SEP2017A, and C-3-12SEP2017A

Treated Cotton/Poly Blend Fabric: CP-1-12SEP2017A, CP-2-12SEP2017A, and CP-3-12SEP2017A

2. MRID 504405-03 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *S. aureus*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1810.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (C-1-12SEP2017A, C-2-12SEP2017A, and C-3-12SEP2017A) of "Treated Cotton Fabric", were tested according to Microchem Protocol P1938 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

3. MRID 504405-04 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *S. aureus*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1813.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (CP-1-12SEP2017A, CP-2-12SEP2017A, and CP-3-12SEP2017A) of "Treated Cotton/Poly Blend Fabric", were tested according to Microchem Protocol PP1994 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, 24 hours, 48 hours, and 72 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

4. MRID 504405-05 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *S. aureus*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1814.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (M-1-11SEP2017A, M-2-11SEP2017A, and M-3-11SEP2017A) of "Treated Microfiber Fabric", were tested according to Microchem Protocol P2005 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 ± 4 hours and all study controls were incubated for 48 ± 2 hours at $36\pm1^{\circ}\text{C}$.

5. MRID 504405-06 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *K. pneumoniae*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1811.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Three lots (C-1-12SEP2017A, C-2-12SEP2017A, and C-3-12SEP2017A) of "Treated Cotton Fabric", were tested according to Microchem Protocol P1979 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at $36\pm1^{\circ}\text{C}$ for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24

hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 \pm 4 hours and all study controls were incubated for 48 \pm 2 hours at 36 \pm 1°C.

6. MRID 504405-07 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *K. pneumoniae*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1812.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Three lots (CP-1-12SEP2017A, CP-2-12SEP2017A, and CP-3-12SEP2017A) of "Treated Cotton/Poly Blend Fabric", were tested according to Microchem Protocol PP1993 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at 36 \pm 1°C for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, 24 hours, 48 hours, and 72 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 \pm 4 hours and all study controls were incubated for 48 \pm 2 hours at 36 \pm 1°C.

7. MRID 504405-08 "Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against *K. pneumoniae*", by Elizabeth Richard. Study conducted at Microchem Laboratory. Study completion date – 14 NOV 2017. Laboratory Project Number GLP1815.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Three lots (M-1-11SEP2017A, M-2-11SEP2017A, and M-3-11SEP2017A) of "Treated Microfiber Fabric", were tested according to Microchem Protocol P2006 (copy provided). Three carriers per lot per contact time were inoculated with 1 ml of microorganism culture, wrapped and incubated at 36 \pm 1°C for 30 min, 1 hour, 2 hours, 3 hours, 6 hours, and 24 hours. Upon completion of the contact time, carriers were harvested into twenty (20) ml of neutralizing broth (Dey Engley (D/E) broth). All tubes containing test or control fabric were vortex mixed for 2 minutes \pm 5 seconds. Neutralizing broth was enumerated using standard pour plating techniques. All plates for test and control fabrics were incubated for 48 \pm 4 hours and all study controls were incubated for 48 \pm 2 hours at 36 \pm 1°C.

V. RESULTS

MRID	Organism	Lot #	Controls	% Reduction							
				30 min.	1 hr.	2 hrs.	3 hrs.	6 hrs.	24 hrs.	48 hrs.	72 hrs.
Treated Cotton Fabrics											
50440 5-03	<i>Staphylococcus aureus</i> (ATCC 6538)	C-1- 12SEP2017A	3.6 x 10 ⁵ 1.03 x 10 ⁶	56.09	89.43	98.22	99.86	>99.99	>99.99	-	-
		C-2- 12SEP2017A		65.90	75.99	99.16	99.54	>99.9	>99.99	-	-
		C-3- 12SEP2017A		57.66	90.60	98.49	>99.9	>99.9	>99.99	-	-
50440 5-06	<i>Klebsiella pneumoniae</i> (ATCC 4352)	C-1- 12SEP2017A	5.25 x 10 ⁵ 1.09 x 10 ⁶	32.56	38.61	99.77	>99.9 9	>99.99 99	>99.99 999	-	-
		C-2- 12SEP2017A		32.09	69.24	99.68	>99.9 9	>99.99 9	>99.99 999	-	-
		C-3- 12SEP2017A		0	45.32	99.68	>99.9 9	>99.99 99	>99.99 999	-	-
Treated Microfiber Fabrics											
50440 5-05		M-1- 11SEP2017A	4.5 x 10 ⁵	61.36	95.83	99.70	>99.9	>99.9	-	-	-

MRID	Organism	Lot #	Controls	% Reduction							
				30 min.	1 hr.	2 hrs.	3 hrs.	6 hrs.	24 hrs.	48 hrs.	72 hrs.
	<i>Staphylococcus aureus</i> (ATCC 6538)	M-2-11SEP2017A	4.33 x 10 ⁵	41.59	97.45	99.56	99.51	>99.9	-	-	-
		M-3-11SEP2017A		72.04	91.79	99.49	>99.9	>99.9	-	-	-
50440 5-08	<i>Klebsiella pneumoniae</i> (ATCC 4352)	M-1-11SEP2017A	3.58 x 10 ⁵	24.70	98.14	>99.9	>99.9	>99.99	>99.99	-	-
		M-2-11SEP2017A	1.79 x 10 ⁵	54.65	97.23	>99.9	>99.9	>99.99	>99.99	-	-
		M-3-11SEP2017A	10 ⁵	86.04	99.77	>99.9	>99.9	>99.99	>99.99	-	-
Treated Cotton/Poly Blend Fabrics											
50440 5-04	<i>Staphylococcus aureus</i> (ATCC 6538)	CP-1-12SEP2017A	5.89 x 10 ⁵	46.29	65.06	95.07	99.03	>99.99	>99.99	>99.9999	>99.9999
		CP-2-12SEP2017A	6.71 x 10 ⁵	53.33	98.44	99.87	99.18	>99.99	>99.99	>99.9999	>99.9999
		CP-3-12SEP2017A	10 ⁵	35.05	70.17	99.82	99.55	99.99	>99.99	>99.9999	>99.9999
50440 5-07	<i>Klebsiella pneumoniae</i> (ATCC 4352)	CP-1-12SEP2017A	1.57 x 10 ⁶	40.10	66.92	99.88	>99.9	>99.99	>99.99	>99.9999	>99.9999
		CP-2-12SEP2017A	1.04 x 10 ⁶	37.87	96.39	>99.99	>99.9	>99.99	>99.99	>99.9999	>99.9999
		CP-3-12SEP2017A	10 ⁶	50.25	92.48	>99.9	>99.9	>99.99	>99.99	>99.9999	>99.9999

VI. CONCLUSIONS

MRID #	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support label claims?
504405-02 - 504405-08	Residual Bacterial Reduction for Post Laundry Contaminations	Laundered Dried Fabrics/Textiles	0.0000310 ration for polyester, 0.0000155 for cotton, and 0.0000207 for blend.	23-minute rinse cycle with 2-minute soaking time; and 55-minute drying time	No	200ppm hard tap water	<ul style="list-style-type: none"> <i>Staphylococcus aureus</i> (ATCC 6538) <i>Klebsiella pneumoniae</i> (ATCC 4352) 	

VII. LABEL

Proposed Label dated November 17, 2017


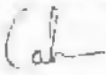
1. The proposed label claims that the product, SilvaClean (EPA Reg. No. 90335-1), provides ongoing residual self-sanitizing activity against *Staphylococcus aureus* and *Klebsiella pneumoniae* on cotton, cotton/polyester blend and microfiber materials until the next laundering event. **These claims are not acceptable as they are not supported by the submitted data.**

All claims for residual self-sanitizing activity should be removed. The following provide rationale as to why these claims are not acceptable:

- To make label claims as a "Sanitizer" a product should demonstrate a 3-log reduction at a contact time ≤ 5 minutes.
 - o A 3-log reduction was not achieved for any of the fabric types at a 30-minute contact time
- Claims for "ongoing" are synonymous with continuous and testing to support these claims should include re-inoculation steps.

2. The applicant must make the following changes to the proposed label, as appropriate:

- Remove all claims and associated directions for use as a "residual self-sanitizer"
- Remove all claims for "self-sanitizing" and any mention of specific microorganisms (e.g. *Staphylococcus aureus* and *Klebsiella pneumoniae*).
- Remove the optional marketing claims for healthcare and sports

 <div style="display: inline-block; text-align: center;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Registration Amendment Other	OPP Identifier Number
Application for Pesticide - Section I				
1. Company/Product Number 90335-1		2. EPA Product Manager Zeno Bain		3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Applied Silver, Inc. / SilvaClean		PM# 33		
5. Name and Address of Applicant (Include Zip Code) Applied Silver, Inc. 26254 Eden Landing Road Hayward, CA 94545 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____		
Section - II				
<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <input type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below. </div> <div style="width: 48%;"> <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other - Explain below. </div> </div>				
Explanation: Use additional page(s) if necessary. (For Section I and Section II) In response to the deficiencies listed in EPA's <i>Technical Screen Failure</i> letter received on January 17, 2018, enclosed is a volume that supplements information for GLP study, MRID 50440502.				
Section - III				
1. Material This Product Will Be Packaged In:				
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				
Section - IV				
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name Sheryl Lindros Dolan		Title Agent		Telephone No. (Include Area Code) (202) 266-5031; sdolan@actagroup.com
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				6. Date Application Received (Stamped)
2. Signature 		3. Title Director of Regulatory Affairs		
4. Typed Name William Morris		5. Date January 23, 2018		



January 23, 2018

Via CDX

Mr. Zeno Bain
Antimicrobials Division (7510P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard 7510P
2777 S. Crystal Drive
Arlington, VA 22202

Re: Response to Technical Screen Deficiency Letter, Decision Number 536139

Dear Mr. Bain:

In response to the U.S. Environmental Protection Agency's (EPA) January 17, 2018, letter, Applied Silver, Inc. (ASI) is pleased to submit the accompanying information that supplements the recently submitted Good Laboratory Practice (GLP) study, *Treating Fabric with Self-Sanitizing Laundry Test Solution*, MRID 50440502, in response to the issues that EPA outlined in its letter. This information is submitted in support of ASI's pending amendment application for its registered product, SilvaClean[®], EPA Reg. No. 90335-1.

Included with this letter are the following documents:

- Transmittal Document;
- EPA Form 8570-1; and
- Volume 1: *Supplemental Information Concerning MRID No. 50440502.*

With this submission, ASI responds to all the issues that EPA raised in its January 17, 2018, letter.

If there are any questions or comments regarding this submission, please contact Sheryl Lindros Dolan, The Acta Group, at (202) 266-5031 or sdolan@actagroup.com.

Sincerely,

A handwritten signature in black ink, appearing to read "William Morris".

William Morris
Director of Regulatory Affairs

Attachments

{01433.001 / 111 / 00231343.DOCX 2}

Applied Silver Inc.
26254 Eden Landing Road
Hayward, CA 94545
888-939-4747

Transmittal DocumentName and Address of Submitter:

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Company No.: 90335
Contact Person: William Morris
Title: Director of Regulatory Affairs
Telephone: 1 (888) 939 4747 x 149
E-Mail: bill@appliedsilver.com

Individual to be contacted, if necessary, to process this application:

The Acta Group, L.L.C.
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, D.C. 20037-1701

Contact Person: Sheryl Lindros Dolan
Telephone: (202) 266-5031
Fax: (202) 557-3836
E-Mail: sdolan@actagroup.com

Regulatory Actions: Pursuant to a Preliminary Technical Screen Deficiency letter dated January 17, 2018, Decision No. 536139, Applied Silver, Inc. (ASI) is submitting supplemental information for a previously-submitted GLP study, MRID 50440502, in response to questions from EPA.

Transmittal Date: January 23, 2018

List of Submitted Studies:

Vol.	Guideline No.	Study Report Title	MRID No.
1	N/A	<i>Supplemental Information Concerning MRID No. 50440502, Report No. 1433.001-02, January 23, 2018, 11 p.</i>	50504501



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

U.S. EPA
Regulatory Affairs Division

January 17, 2018

William Morris
Director
Regulatory Affairs
Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Subject: Technical Screen Failure
Product Name: SilvaClean
EPA Registration Number: 90335-1
Application Date: 11/17/2017
Decision Number: 536139

Dear Mr. Morris:

The U.S. Environmental Protection Agency (Agency or EPA) has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). The EPA has determined that your application has not passed the preliminary technical screening and therefore is subject to rejection if the application is not corrected.

- Please confirm that the substance identified as "Test Solution" in MRID 50440502 is the subject product.
- The water-to-fabric ratio in the washing machine that was used to treat the fabrics was not identified. What volume of water was present in the washing machine when the treatment solution was added?
- Would the modification made to the washing machine in order to add the treatment solution be necessary for normal use? How would users be able to control when the solution is added to the wash load?

In order for the review of your pesticide product to continue, you will need to correct your application to address the items listed above within 10 business days of the date you received this letter. The EPA recommends sending your correction by email to the contact listed below to ensure it is received in a timely manner. If studies or confidential business information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application or do not respond within 10 business days, your application will be rejected. At this time, you could also choose to withdraw your application.

Page 2 of 2
EPA Reg. No. 90335-1
Decision No. 536139

If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at heffernan.aline@epa.gov.

Sincerely,

Zeno Bain, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Efficacy Technical Screen Memo

Technical Screen

EPA Reg#/File Symbol: 90335-1		E-Sub #: 24426	
DP Barcode: 444670		Submission #: 1012169	
Product name: SilvaClean		Registrant: Applied Silver, Inc.	
Reviewer's name: Alison Clune		Risk Manager: Zeno Bain/Aline Heffernan	
Completion due date: 1/15/18		Completion Date: 12/22/17	
Formulation type: Liquid <input checked="" type="checkbox"/> ; Towelettes <input type="checkbox"/> ; Spray <input type="checkbox"/> ; Solid <input type="checkbox"/> ; Textile <input type="checkbox"/> ; Aerosol <input type="checkbox"/> ; Other _____			
Sterilant: <input type="checkbox"/>	Disinfectant: <input type="checkbox"/>	FC Sanitizer: <input type="checkbox"/>	NF Sanitizer <input type="checkbox"/> TB: <input type="checkbox"/> Fungicidal: <input type="checkbox"/> Virucide: <input type="checkbox"/>
MRID(s): 50440501-50440508			
PC Code(s)	Active Ingredient Names	% wt (label)	%LCL
072501	Silver	22.5%	
Label Claims: Laundry additive residual self-sanitizer – Dilute concentrate 0.024, 0.032, or 0.048 oz with 100 lbs cotton, cotton/poly blend, or microfiber fabric, respectively, in 500 or 1000 mL distilled or deionized water in the final rinse cycle, allowing to soak at least 2 minutes. Effective time not specified.			
Product Lot(s)	Tested Concentration(s)	Tested at LCL	
170821-1	22.2%, diluted to 21.69%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
170821-2	22.2%, diluted to 21.69%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
170821-3	22.2%, diluted to 21.69%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Tested: RTU <input type="checkbox"/> Diluted <input checked="" type="checkbox"/>		Tested Dilution Rate: Cotton: 0.00071 fl oz test solution to ~3 lbs fabric Cotton/Poly: 0.00078 fl oz test solution to 2.5 lbs fabric Microfiber: 0.0029 fl oz test solution to ~6 lbs fabric Soak time: 2 minutes +/- 4 seconds Tested time intervals: 0, 30 min, 1, 2, 3, 6, 24 hours (+ 48 and 72 hours for cotton/poly only)	
Certificate of Analysis: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		Performed by testing Lab: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
Test Lab: Microchem Laboratory			
Comments: Efficacy Review: Efficacy data submissions to support residual self-sanitizing efficacy of treated cotton, cotton/polyester, and microfiber fabrics against <i>Klebsiella pneumoniae</i> and <i>Staphylococcus aureus</i> . Product is NOT cleared for technical screen. The following need to be addressed: <ul style="list-style-type: none"> Please confirm that the substance identified as "Test Solution" in MRID 50440502 is the subject product. 			

- What was the water-to-fabric ratio in the washing machine that was used to treat the fabrics for testing? What volume of water was present in the washing machine when the treatment solution was added?
- Would the modification made to the washing machine in order to add the treatment solution be necessary for normal use? How would users be able to control when the solution is added to the wash load?

A570 - Label amendment requiring data submission

- Must submit Group A and B product chemistry data to support a change in the manufacturing process
- Addition of public health pests requires efficacy data.
- Change in signal word requires acute toxicity data be submitted and/or referenced.
- Change from a registered to an unregistered source.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition	✓		
830.1600	Description of materials used to produce the product	✓		
830.1650	Description of formulation process	✓		
830.1670	Discussion on the formation of impurities	✓		
830.1700	Preliminary analysis	✓		
830.1750	Certified limits (158.345)	✓		
830.1800	Enforcement analytical method	✓		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color	✓		
830.6303	Physical State	✓		
830.6304	Odor	✓		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓		
830.6315	Flammability	✓		
830.6316	Explosibility	✓		
830.6317	Storage stability*	✓		
830.6319	Miscibility	✓		
830.6320	Corrosion Characteristics*	✓		
830.6321	Dielectric Breakdown Voltage	✓		
830.7000	pH	✓		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	✓		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	✓		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required

*May not be included with initial application

A570 – Acute Toxicity Requirements

- Change in signal word requires acute toxicity data be submitted and/or referenced.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)		✓		
830.1200	Acute Dermal (LD50)		✓		
830.1300	Acute Inhalation (LC50)		✓		
830.2400	Acute Eye Irritation		✓		
830.2500	Acute Dermal Irritation		✓		
830.2600	Dermal Sensitization		✓		

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 11-17-17

Experts In-Processing Signature: BB Date 11-30-17 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date

EPA Reg. Number: <u>90335-1</u>		EPA Receipt Date: <u>11-17-17</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type		<input checked="" type="checkbox"/>		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)				<input checked="" type="checkbox"/>
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes <input type="checkbox"/>	no <input type="checkbox"/>		
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)		<input checked="" type="checkbox"/>		
	Certificate and data matrix consistent		<input checked="" type="checkbox"/>		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes <input type="checkbox"/>	no <input type="checkbox"/>		
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)				<input checked="" type="checkbox"/>
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)		<input checked="" type="checkbox"/>		
5	a) Selective Method (Fee category experts use)	yes <input checked="" type="checkbox"/>	no <input type="checkbox"/>		
	b) Cite-All (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>		
	c) Applicant owns all data (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>		
6	5 Copies of <u>Label</u> (<u>Electronic labels on CD</u> are encouraged and guidance is available)		<input checked="" type="checkbox"/>		
7	Is the data package consistent with <u>PR Notice 86-5</u>		<input checked="" type="checkbox"/>		
8	Notice of Filing included with petitions				<input checked="" type="checkbox"/>

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: Pass

-All required forms are complete.

INEAs: N/A

-NO CSF

1-3: Pass

-MRID 504405

Status: Pass

-MS 12/05/17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 29, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-536139
EPA File Symbol or Registration Number: 90335-1
Product Name: SilvaClean
EPA Receipt Date: 17-Nov-2017
EPA Company Number: 90335
Company Name: APPLIED SILVER, INC.

MS. SHERYL LINDROS DOLAN
THE ACTA GROUP
APPLIED SILVER, INC.
26254 EDEN LANDING ROAD
HAYWARD, CA 94545

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A570

AMENDMENT;NON-FAST TRACK;REQUIRING DATA REVIEW;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8154.

Sincerely,

A handwritten signature in dark ink, appearing to be "JLL", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Free for Service

{1012169Q~

This package includes the following

for Division

- New Registration

Ⓢ Amendment

© AD

- BPPD

RD

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

Risk Mgr.	33
-----------	----

Receipt No.

S-

1012169

EPA File Symbol/Reg. No.

90335-1

Pin-Punch Date:

11/17/2017

This item is NOT subject to FFS action.

Action Code:

Parent/Child Decisions:

Requested:

Granted:

Amount Due: \$ 7.00

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: _____ Date: _____

Remarks:

Sheryl Dolan

From: Bill Morris <bill@appliedsilver.com>
Sent: Friday, November 03, 2017 4:17 PM
To: Sheryl Dolan; Priya Balachandran
Subject: Fwd: Pay.gov Payment Confirmation: PRIA Service Fees

FYI,

PRIA payment confirmation below.

----- Forwarded message -----

From: <notification@pay.gov>
Date: Fri, Nov 3, 2017 at 1:15 PM
Subject: Pay.gov Payment Confirmation: PRIA Service Fees
To: bill@appliedsilver.com

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 265PF96M
Agency Tracking ID: 75356591803
Transaction Type: Sale
Transaction Date: 11/03/2017 04:15:08 PM EDT

Account Holder Name: Juinan Wang

Transaction Amount: \$3,831.00
Card Type: MasterCard
Card Number: *****4291

Registration Number: 90335-1
Company Name: Applied Silver, Inc.
Company Number: 90335
Action Code: A570

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

--
Bill Morris
Founder and Director of Regulatory

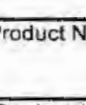
Applied Silver, Inc.

26254 Eden Landing Road, Hayward, CA 94545
Email: bill@appliedsilver.com
Office: 1 (888) 939 4747 x 149 ; Mobile: (415) 652 2694



DISCLAIMER: EPA regulated products containing SilvaClean™ solely protect the finished product itself from stain- and odor- causing bacteria, mold, and mildew. Products containing SilvaClean are not approved by the EPA to make public health claims.

CONFIDENTIALITY WARNING: The contents of this e-mail and any attachment are the property of Applied Silver, Inc., and are intended for the addressee only. Any reader of this message who is not the intended recipient or the employee or agent responsible to deliver to the intended recipient, is notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you receive this communication in error please notify us immediately and delete all copies from your computer system.

 <div style="display: inline-block; text-align: center;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">X</div> <div style="border: 1px solid black; padding: 2px;">Other</div>	<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">Registration</div> <div style="border: 1px solid black; padding: 2px;">Amendment</div>	<div style="border: 1px solid black; padding: 2px;">OPP Identifier Number</div>
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Application for Pesticide - Section I

1. Company/Product Number 90335-1	2. EPA Product Manager Zeno Bain	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SilvaClean®	PM# 33	
5. Name and Address of Applicant (Include Zip Code) Applied Silver, Inc. 26254 Eden Landing Road Hayward, CA 94545 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
--	---

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

This application is an amendment to add residual self-sanitizing claims to the label for SilvaClean®, EPA Reg. No. 90335-1. Applied Silver expects that EPA will place this application into PRIA 3, Category A570, with a fee of \$3,831.00 and a 4-month review period.


Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If "Yes" Unit Packaging wgt. No per container	If "Yes" Package wgt No. per container	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted					

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1 and 2 liters	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Sheryl Lindros Dolan	Title Agent	Telephone No. (Include Area Code) (202) 266-5031

Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.	6. Date Application Received <div style="text-align: center;">(Stamped)</div>
2. Signature 	3. Title Director, Regulatory Affairs
4. Typed Name William Morris	5. Date November 17, 2017



November 17, 2017

Via CDX Electronic Submission

Mr. Zeno Bain
Document Processing Desk
U.S. Environmental Protection Agency
Office of Pesticide Programs
7504P, Room S-4900
One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Re: Application to Amend SilvaClean® Registration, EPA Reg. No. 90335-1

Dear Mr. Bain:

Applied Silver, Inc. (ASI) is pleased to submit to the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) Antimicrobial Division (AD) the accompanying application to amend SilvaClean®, EPA Reg. No. 90335-1, which currently is registered for application to textiles after each laundering to protect fibers against stain- and odor-causing bacteria, mold, and mildew.

As discussed during the October 24, 2017, pre-submission meeting with OPP, ASI is submitting an application to add residual self-sanitizing laundry additive claims to its product, consistent with Office of Chemical Safety and Pollution Prevention (OCSPP) Guideline 810.2400(e)(1). Consistent with the Guideline, SilvaClean was used to treat three fabric types (cotton, cotton/polyester blend, and microfiber) in a simulated use test, where it was added to fabric in the final step of a laundering process. Consistent with the Guideline, efficacy testing then was conducted on the treated fabric according to AATCC Method 100-2012 for the following microorganisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). The results of the Good Laboratory Practice (GLP) simulated use test and the successful efficacy testing are presented in the accompanying Volumes 2-8.

Accompanying this submission are the following supporting documents:

- Transmittal document;
- Pesticide Registration Improvement Extension Act (PRIA 3) fee payment receipt;

Applied Silver Inc.
26254 Eden Landing Road
Hayward, CA 94545
888-939-4747

- Proposed label (redlined and clean versions);
- EPA Forms 8570-1, 8570-34, and 8570-35 (confidential and public versions);
- Volume 1: A discussion volume that reviews the efficacy testing and proposed claims, and includes copies of correspondence and related documentation exchanged with EPA pertinent to this amendment application.
- Volume 2: the simulated use study, *Treating Fabric with Self-Sanitizing Laundry Test Solution*.
- Volumes 3-8: efficacy studies, for the two microorganisms on the three fabric types.

ASI looks forward to working with the Antimicrobial Division to make this first in a series of product amendments. If there are any questions or comments about this submission, please contact Sheryl Lindros Dolan, The Acta Group, at (202) 266-5031 or sdolan@actagroup.com.

Sincerely,

A handwritten signature in dark ink, appearing to be 'Bill Morris', written over a horizontal line.

Bill Morris
Director of Regulatory Affairs
Applied Silver, Inc.

Attachment (Transmittal Document)

cc: Mr. John Hebert

Mr. Seiichi Murasaki

Applied Silver Inc.
26254 Eden Landing Road
Hayward, CA 94545
888-939-4747

Transmittal DocumentName and Address of Submitter:

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Company No.: 90335
Contact Person: William Morris
Title: Director, Regulatory Affairs
Telephone: 1 (888) 939 4747 x 149
E-Mail: bill@appliedsilver.com

Individual to be contacted, if necessary, to process this application:

The Acta Group, L.L.C.
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, D.C. 20037-1701

Contact Person: Sheryl Lindros Dolan
Telephone: (202) 266-5031
Fax: (202) 557-3836
E-Mail: sdolan@actagroup.com

Regulatory Actions: This application is an amendment to add residual self-sanitizing claims to the label for SilvaClean[®], EPA Reg. No. 90335-1. Applied Silver expects that EPA will place this application into PRIA 3, Category A570, with a fee of \$3,831.00 and a 4-month review period.

Transmittal Date: November 17, 2017

List of Submitted Studies:

Vol.	Contents	Guideline No.	Study Report Title	MRID No.
1	Amendment Overview and Discussion of Proposed Label Claims	N/A	<i>Amendment Overview and Discussion of Proposed Label Claims</i> , Report No. 1433.001-01, November 17, 2017, 204 p.	50440501
2	Simulated Use Data	810.2400(e)(1)	Treating Fabric with Self-Sanitizing Laundry Test Solution, Microchem Laboratory, Report No. GLP1777, November 14, 2017, 33 p.	50440502
3	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>S. aureus</i> , Treated Cotton Fabric, Microchem Laboratory, Report No.	50440503

Vol.	Contents	Guideline No.	Study Report Title	MRID No.
			GLP1810, November 14, 2017, 51 p.	
4	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>S. aureus</i> , Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP1813, November 14, 2017, 53 p.	50440504
5	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>S. aureus</i> , Treated Microfiber Fabric, Microchem Laboratory, Report No. GLP1814, November 14, 2017, 47 p.	50440505
6	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>K. pneumoniae</i> , Treated Cotton Fabric, Microchem Laboratory, Report No. GLP1811, November 14, 2017, 48 p.	50440506
7	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>K. pneumoniae</i> , Treated Cotton/Poly Blend Fabric, Microchem Laboratory, Report No. GLP1812, November 14, 2017, 53 p.	50440507
8	Residual Self Sanitizing Efficacy Data	810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>K. pneumoniae</i> , Treated Microfiber Fabric, Microchem Laboratory, Report No. GLP1815, November 14, 2017, 47 p.	50440508



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date November 17, 2017	EPA Reg No./ File Symbol: 90335-1	Page 1 of 4
Applicant's/Registrant's Name and Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	

Ingredient: Silver (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Product Chemistry					
OCSPP 830.1550	Product Identity and Composition	49270902	Applied Silver Inc.	OWN	
OCSPP 830.1600	Description of Materials Used to Produce the Product	49270902	Applied Silver Inc.	OWN	
OCSPP 830.1620	Description of Production Process	49270902	Applied Silver Inc.	OWN	
OCSPP 830.1650	Description of Formulation Process	49270902	Applied Silver Inc.	OWN	
OCSPP 830.1670	Discussion of Formulation of Impurities	49270902	Applied Silver Inc.	OWN	
OCSPP 830.1700	Preliminary Analysis – Silver	49270903	Applied Silver Inc.	OWN	
OCSPP 830.1700	Preliminary Analysis – Silver	49270904	Applied Silver Inc.	OWN	
OCSPP 830.1700	Preliminary Analysis – Impurities	49270905	Applied Silver Inc.	OWN	
OCSPP 830.1700	Preliminary Analysis – Impurities	49270906	Applied Silver Inc.	OWN	
OCSPP 830.1750	Certified Limits	49270902	Applied Silver Inc.	OWN	
OCSPP 830.1800	Enforcement Analytical Method	49270902	Applied Silver Inc.	OWN	
OCSPP 830.6302	Color	49270907	Applied Silver Inc.	OWN	
OCSPP 830.6303	Physical State	49270907	Applied Silver Inc.	OWN	
OCSPP 830.6304	Odor	49270907	Applied Silver Inc.	OWN	
OCSPP 830.6313	Stability to normal and elevated temps, metals, ions	49270901	Applied Silver Inc.	OWN	
OCSPP 830.6314	Oxidation/Reduction chemical incompatibility	49270907	Applied Silver Inc.	OWN	
OCSPP 830.6315	Flammability	49270901	Applied Silver Inc.	OWN	
OCSPP 830.6316	Explosibility	49270901	Applied Silver Inc.	OWN	

Signature	Name and Title William Morris, Director, Regulatory Affairs	Date 11/17/2017
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1200 Pennsylvania Avenue, N.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date November 17, 2017	EPA Reg No./ File Symbol: 90335-1	Page 2 of 4
Applicant's/Registrant's Name and Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	

Ingredient: Silver (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OCSPP 830.6317	Storage Stability	49270908	Applied Silver Inc.	OWN	
OCSPP 830.6319	Miscibility	49270901	Applied Silver Inc.	OWN	
OCSPP 830.6320	Corrosion Characteristics	49270908	Applied Silver Inc.	OWN	
OCSPP 830.6321	Dielectric Breakdown Voltage	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7000	pH	49270907	Applied Silver Inc.	OWN	
OCSPP 830.7100	Viscosity	49270907	Applied Silver Inc.	OWN	
OCSPP 830.7200	Melting Point/Melting Range	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7220	Boiling Point/Boiling Range	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7300	Density/Relative Density/Bulk	49270907	Applied Silver Inc.	OWN	
OCSPP 830.7370	Dissociation Constant	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7520	Particle Size, Fiber Strength, Diameter Distribution	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7550	Particle Coefficient (n-Ocl/H2O) shake flask	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7560	Particle Coefficient (n-Ocl/H2O) generator column	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7570	Particle Coefficient (n-Ocl/H2O) estimation by liquid	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7840	Water Solubility: column elation/shake flask method	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7860	Water Solubility: generator column method	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7950	Vapor Pressure	49270901	Applied Silver Inc.	OWN	
OCSPP 830 Series	Product Chemistry Discussion and Data Waivers	49270901	Applied Silver Inc.	OWN	

Signature [Signature]	Name and Title William Morris, Director, Regulatory Affairs	Date 11/17/2017
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DATA MATRIX

Date November 17, 2017	EPA Reg No./ File Symbol: 90335-1	Page 3 of 4
Applicant's/Registrant's Name and Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	

Ingredient: Silver (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Acute Toxicity					
OCSPP 870.1100	Acute Oral Toxicity	49270910	Applied Silver Inc.	OWN	
OCSPP 870.1200	Acute Dermal Toxicity	49270911	Applied Silver Inc.	OWN	
OCSPP 870.1300	Acute Inhalation Toxicity	49270912	Applied Silver Inc.	OWN	
OCSPP 870.2400	Primary Eye Irritation	49270909	Applied Silver Inc.	OWN	
OCSPP 870.2500	Primary Skin Irritation	49270913	Applied Silver Inc.	OWN	
OCSPP 870.2600	Skin Sensitization	49270909	Applied Silver Inc.	OWN	
OCSPP 870 Series	Toxicity Discussion and Waiver Requests	49270909	Applied Silver Inc.	OWN	
Efficacy					
(no guideline)	Silver Uptake in Textile	49270915	Applied Silver Inc.	OWN	
OCSPP 810.2400(e)(1)	Simulated Use Data – Treating Fabric with Self-Sanitizing Laundry Test Solution	50440502	Applied Silver Inc.	OWN	
OCSPP 810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>S. aureus</i> , Treated Cotton Fabric	50440503	Applied Silver Inc.	OWN	
OCSPP 810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>S. aureus</i> , Treated Cotton/Poly Blend Fabric	50440504	Applied Silver Inc.	OWN	
OCSPP 810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>S. aureus</i> , Treated Microfiber Fabric	50440505	Applied Silver Inc.	OWN	

Signature 	Name and Title William Morris, Director, Regulatory Affairs	Date 11/17/2017
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DATA MATRIX

Date November 17, 2017	EPA Reg No./ File Symbol: 90335-1	Page 4 of 4
Applicant's/Registrant's Name and Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	

Ingredient: Silver (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OCSP 810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>K. pneumoniae</i> , Treated Cotton Fabric	50440506	Applied Silver Inc.	OWN	
OCSP 810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>K. pneumoniae</i> , Treated Cotton/Poly Blend Fabric	50440507	Applied Silver Inc.	OWN	
OCSP 810.2400(e)(1)	Evaluating Self-Sanitizing Fabric using the AATCC 100 Method against <i>K. pneumoniae</i> , Treated Microfiber Fabric	50440508	Applied Silver Inc.	OWN	

Signature	Name and Title William Morris, Director, Regulatory Affairs	Date 11/17/2017
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DATA MATRIX

Date November 17, 2017	EPA Reg No./ File Symbol: 90335-1	Page 1 of 5
Applicant's/Registrant's Name and Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	
Ingredient: Silver (TGAI)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Generic Data Requirements					
Product Chemistry					
Group A					
OCSPP 830.1550	Product Identity and Composition	49270901	Applied Silver Inc.	OWN	
OCSPP 830.1600	Description of Materials Used to Produce the Product	49270901	Applied Silver Inc.	OWN	
OCSPP 830.1620	Description of Production Process	49270902	Applied Silver Inc.	OWN	
OCSPP 830.1650	Description of Formulation Process	49270901	Applied Silver Inc.	OWN	
OCSPP 830.1670	Discussion of Formation of Impurities	49270901	Applied Silver Inc.	OWN	
OCSPP 830.1700	Preliminary Analysis	49270902	Applied Silver Inc.	OWN	
OCSPP 830.1750	Certified Limits	49270901	Applied Silver Inc.	OWN	
OCSPP 830.1800	Enforcement Analytical Method	49270901	Applied Silver Inc.	OWN	
Group B					
OCSPP 830.6302	Color	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.6303	Physical State	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.6304	Odor	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.6313	Stability to normal and elevated temps, metals, ions	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.6314	Oxidation/Reduction: chemical incompatibility	49270901	Applied Silver Inc.	OWN	
OCSPP 830.6315	Flammability	49270901	Applied Silver Inc.	OWN	
OCSPP 830.6316	Explosibility	49270901	Applied Silver Inc.	OWN	

Signature	Name and Title William Morris, Director, Regulatory Affairs	Date 11/17/2017
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DATA MATRIX

Date November 17, 2017	EPA Reg No./ File Symbol: 90335-1	Page 2 of 5
Applicant's/Registrant's Name and Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	

Ingredient: Silver (TGA)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OCSPP 830.6317	Storage Stability	49270901	Applied Silver Inc.	OWN	
OCSPP 830.6319	Miscibility	49270901	Applied Silver Inc.	OWN	
OCSPP 830.6320	Corrosion Characteristic	49270901	Applied Silver Inc.	OWN	
OCSPP 830.6321	Dielectric Breakdown Voltage	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7000	pH	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.7050	UV/Visible light spectrum	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.7100	Viscosity	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7200	Melting Point/Melting Range	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.7220	Boiling Point/Boiling Range	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.7300	Density/Relative Density/Bulk Density	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.7370	Dissociation Constant	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7520	Particle Size, Fiber Strength, Diameter Distribution	49270901	Applied Silver Inc.	OWN	
OCSPP 830.7550	Partition Coefficient (n-Oct/H ₂ O) shake flask	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.7560	Partition Coefficient (n-Oct/H ₂ O) generator column	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.7570	Partition Coefficient (n-Oct/H ₂ O) estimation by liquid	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.7840	Water Solubility: column elution/shake flask method	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.7860	Water Solubility: generator column method	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 830.7950	Vapor Pressure	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1

Signature	Name and Title William Morris, Director, Regulatory Affairs	Date 11/17/2017
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DATA MATRIX

Date November 17, 2017	EPA Reg No./ File Symbol: 90335-1	Page 3 of 5
Applicant's/Registrant's Name and Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	

Ingredient: Silver (TGA)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Acute Toxicity Testing					
OCSPP 870.1100	Acute Oral Toxicity	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 870.1200	Acute Dermal Toxicity	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 870.1300	Acute Inhalation Toxicity	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 870.2400	Primary Eye Irritation	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 870.2500	Primary Dermal Irritation	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 870.2600	Skin Sensitization	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
Development Toxicity &					
OCSPP 870.3700	Prenatal Developmental Toxicity-rat and rabbit	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OSCPP 870.3800	Reproduction and fertility effects	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
Mutagenicity Testing					
OCSPP 870.5100	Bacterial Reverse Mutation Assay	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 870.5300/5375	In vitro mammalian gene mutation	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 870.5385/5395	In vivo cytogenetics	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
Special Testing					
OSCPP 879.7800	Immunotoxicity	49270909	Applied Silver Inc.	OWN	
Nontarget Organism Protection					
OCSPP 850.2100	Acute avian oral toxicity	4331901	Mason Chemical	OLD	
OCSPP 850.1010	Acute toxicity freshwater invertebrates	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1

Signature	Name and Title William Morris, Director, Regulatory Affairs	Date 11/17/2017
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DATA MATRIX

Date November 17, 2017	EPA Reg No./ File Symbol: 90335-1	Page 4 of 5
Applicant's/Registrant's Name and Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	
Ingredient: Silver (TGA)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OCSPP 850.1075	Freshwater fish toxicity	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
Aquatic Organisms Testing					
OCSPP 850.1075/1400	Fish early-life stage	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
OCSPP 850.1300	Aquatic invertebrate life-cycle	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
Nontarget Plant Production					
OCSPP 850.5400	Aquatic plant growth (algae) Tier II (dose response)	RED/Reg. Rev.	EPA RED/Reg. Rev.	PL	1
Environmental Fate					
OCSPP 835.2120	Hydrolysis	49270916	Applied Silver Inc.	OWN	
OCSPP 835.2240	Photodegradation in water	49270916	Applied Silver Inc.	OWN	
OCSPP 850.6800	Activated Sludge Respiration Inhibition Test	49270916	Applied Silver Inc.	OWN	
Applicator Exposure					
OCSPP 875.1100	Dermal Exposure	49270909	Applied Silver Inc.	OWN	
OCSPP 875.1300	Inhalation exposure	49270909	Applied Silver Inc.	OWN	
OCSPP 875.1600	Data reporting and calculations	49270909	Applied Silver Inc.	OWN	
OCSPP 875.1700	Produce use information	49270909	Applied Silver Inc.	OWN	
Post Applicator Exposure					
OCSPP 875.2700	Produce Use Information	49270914	Applied Silver Inc.	OWN	
OCSPP 875.2800	Description of human activity	49270914	Applied Silver Inc.	OWN	
OCSPP 875.2900	Data reporting and calculations	49270914	Applied Silver Inc.	OWN	

Signature	Name and Title William Morris, Director, Regulatory Affairs	Date 11/17/2017
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DATA MATRIX

Date November 17, 2017	EPA Reg No./ File Symbol: 90335-1	Page 5 of 5			
Applicant's/Registrant's Name and Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™				
Ingredient: Silver (TGA)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

NOTES

1. U.S. EPA, *Reregistration Eligibility Document, Silver, List D, Case 4082*, July 1, 1993.
U.S. EPA, *Silver and Compounds, Summary Document (Case 4082 and Case 5015), Registration Review Preliminary Work Plan*, June 2009.
Both available at https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:31::NO:1,3,31,7,12,25:P3_XCHEMICAL_ID:3769

Signature	Name and Title William Morris, Director, Regulatory Affairs	Date 11/17/2017
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CERTIFICATION WITH RESPECT TO CITATION OF DATA

Applicant's/Registrant's Name, Address, and Telephone Number

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

EPA Registration Number/File Symbol

90335-1

Active Ingredient(s) and/or representative test compound(s)

Silver (from silver nitrate)

Date

November 17, 2017

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).



I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)



I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]



I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter, (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Typed or Printed Name and Title

November 17, 2017

William Morris, Director, Regulatory Affairs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 18, 2016

David Swain
Agent for Applied Silver, Inc.
Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Subject: Label Amendment – Correct precautionary statements
Product Name: SilvaClean
EPA Registration Number: 90335-1
Application Date: March 31, 2016
Decision Number: 516138

Dear Mr. Swain:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 90335-1
Decision No. 516138

with FIFRA section 6. If you have any questions, please contact Joe Daniels by phone at (703) 347-8669, or via email at daniels.joseph@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao".

Julie Chao, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Accepted Label

SilvaClean™

Antimicrobial Textile Treatment. SilvaClean™ is an antimicrobial silver treatment for commercial and industrial use on fibers or textiles. SilvaClean™ is effective in inhibiting the growth of bacteria in products to which it is applied. *{These claims may appear on any label panel}*

Products containing SilvaClean™ may not make claims of antimicrobial activity other than protection of the article itself against odor-causing, staining, or deteriorating bacterial in the treated article. This product does not protect users against bacteria, viruses or other disease organisms.

SilvaClean™ is composed of:

Active Ingredient:

Silver*	22.5%
Other Ingredients	77.5%
Total	100.0%

* from silver nitrate.

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive

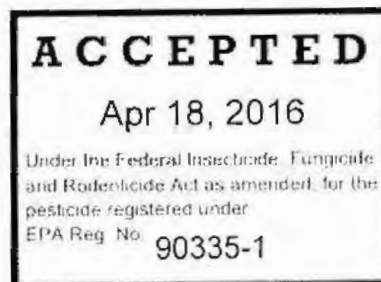
See back panel for first aid and additional precautionary statements.

Net Contents: _____

EPA Reg. No. 90335-1

EPA Est. No. xxx-xx-x

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545



SilvaClean™ is applied to or incorporated into industrial products listed below. For non-food contact uses only.

FOR COMMERCIAL AND INDUSTRIAL USE ONLY. Not for Residential Use.

Textiles made of: cotton and cotton/polyester blend, polyester, nylon, microfiber, spandex, and nylon/spandex blend. Example items include: pillow covers; sheets; blankets; bedspreads; apparel; uniforms; jerseys; active wear; scrubs; lab coats; quilts; liners; curtains; draperies; upholstery; towels; shower curtains; and carpets.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its label.

This product is registered as a microbiostatic agent for material preservation; neither this product nor the articles treated with this product may state or imply any public health claims. Articles or substances treated with this product in accordance with the labeled directions may be exempt from FIFRA regulation pursuant to 40 CFR 152.25(a) if the intended use for incorporating this material into a treated article or substance is for the protection of the article or substance itself.

SilvaClean™ is an antimicrobial silver application that provides 0.00016% to 0.0014% (1.6 ppm – 14 ppm) silver on fibers or textiles. The treatment level of SilvaClean™ for a product will depend on the specific needs of the manufacturer, the textile being treated, and the level and type of performance desired.

Solution Preparation and Treatment: SilvaClean™ is a concentrate that must be diluted with distilled or deionized water before use. Treat textile by soaking in dilute aqueous solution and agitating for at least 2 minutes. Contact Applied Silver, Inc., for dilution and treatment instructions specific to your desired performance.

Textile must be clean prior to the application of product. Retreat textile after each laundering.

STORAGE and DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in a safe manner only in areas inaccessible to small children. Store in original container in dark location. Keep container tightly closed when not in use.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, intermediate mixtures, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA regional office for guidance.

Container Handling: Non-refillable container – do not reuse or refill this container. Return container to Applied Silver, Inc.

PRECAUTIONARY STATEMENTS AND FIRST AID

DANGER

Corrosive

Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid breathing spray or mist. Wear goggles, face shield or safety glasses. Wear chemical-resistant apron over coveralls with long-sleeved shirt and long pants, waterproof gloves covering hands, wrists and lower forearms. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse.

First Aid

If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice.
If on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for treatment advice.
If swallowed:	Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a Poison Control Center or doctor for treatment advice.

For emergency information on SilvaClean™, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the Poison Control Center 1-800-222-1222.

Follow the manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters. This product is toxic to fish and aquatic invertebrates.

From: Chao, Julie <Chao.Julie@epa.gov>
Sent: Sunday, March 20, 2016 9:21 PM
To: dswain@srcconsultants.com; Johnson, Zebora
Cc: therber@srcconsultants.com
Subject: RE: EPA Completed Action

Hi David,

Please submit an amendment through the front-end. We will try to expedite.

Thanks,
Julie

From: dswain@srcconsultants.com [mailto:dswain@srcconsultants.com]
Sent: Saturday, March 19, 2016 1:25 PM
To: Johnson, Zebora <Johnson.Zebora@epa.gov>
Cc: Chao, Julie <Chao.Julie@epa.gov>; therber@srcconsultants.com
Subject: RE: EPA Completed Action

Hi Zebora and Julie,

We have been preparing our state label version after the approval dated 2/23/2016 of the attached amendment for SilvaClean (EPA Reg. No. 90335-1).

As we have reviewed the label we realized we sent in the wrong version of the label for this amendment. The label we sent which you eventually approved on 2/23/16 did not have the correct Precautionary Statements and First Aid. It was a prior version of the label which we were instructed to revise before the initial approval back in 2014.

I have attached a version of the label dated today 3/19/16 which has the correct Precautionary Statements and First Aid which we were instructed to use when the product was first approved by Seichi.

Anyway, we do not think the states will approve the label as approved currently because it doesn't have the Note to Physician and it is a Danger product.

So, is there a way to get the corrected version quickly approved as an amendment? Can you use the attached label and quickly process or should I send in through front end?

Thanks for your help.

Best regards,

David Swain
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

Upcoming OOO – March 21-30, 2016



Introducing SERVICE Portal, a cloud-based gateway to state registration data.
<http://www.sriconsultants.com/services/service-portal>

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

From: Johnson, Zebora [<mailto:Johnson.Zebora@epa.gov>]
Sent: Tuesday, March 01, 2016 3:17 PM
To: dswain@sriconsultants.com
Cc: Chao, Julie; OPP AD Ombudsman
Subject: EPA Completed Action

*Zebora M. Johnson
Registration Risk Manager
Antimicrobials Division
Arlington Va. 22202
Phone (703) 308-7080*

<mailto:Johnson.Zebora@epa.gov>

Scientific & Regulatory Consultants, Inc.

March 31, 2016

Ms. Julie Chao, PM-33
US Environmental Protection Agency
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
Room S4900
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

SUBJECT: SilvaClean™
EPA Reg. No. 90335-1

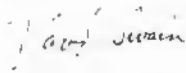
Dear Ms. Chao:

Scientific & Regulatory Consultants, Inc. is submitting a minor label amendment for SilvaClean™, EPA Reg. No. 90335-1 on behalf of Applied Silver, Inc. **No data is being submitted; therefore this is not a PRIA action. NO FEE IS REQUIRED.**

The label amendment re-instates previously accepted text that was inadvertently omitted from the 2/23/16 accepted label (Decision Number 511485). As you indicated in our email correspondence on 3/20/16 (copy attached), we are submitting the revised label as a fast-track amendment, and ask that the review be completed as quickly as possible.

Five (5) clean copies of the label are also enclosed. For any questions or clarification, please contact me immediately at 260-244-6270 or dswain@srcconsultants.com.

Sincerely,



David Swain
Agent for Applied Silver, Inc.

cc: P. McCabe, Applied Silver, Inc.

Enclosure: Email correspondence

SilvaClean™
EPA Reg. No. 90335-1

TRANSMITTAL DOCUMENT

1. Name and address of Submitter:

Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street
Columbia City, IN 46750

AGENT FOR:
Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

2. Regulatory action in support of which this package is submitted:

Fast Track label amendment to add previously accepted label text inadvertently omitted on prior amendment action

This is not a PRIA action. NO FEE IS REQUIRED.

3. Transmittal date:

March 31, 2016

4. Volume 1 Administrative Materials:

- A) Cover letter
- B) Email Correspondence with J. Chao
- C) Application
- E) Five (5) copies of revised labeling

Company Official : David Swain
Agent for Applied Silver, Inc.

Company Name: Applied Silver, Inc.

Company Contact: David Swain
Phone: (260) 244-6270
Fax: (260) 244-6273
Email: dswain@srcconsultants.com

silver could be released before exceeding the acute oral Margin of Exposure (MOE) of 1,000. (See Appendix 1) Since the maximum uptake of silver onto fabric is 14 ppm, the risk for short- and intermediate-term exposure to toddlers who chew on Silva Clean™ treated fabric is not of concern.

SilvaClean™ Acute Toxicology Results and Waivers

Acute toxicology studies were conducted with SilvaClean™. The results of the studies demonstrate this product is classified as Acute Toxicity Category 1. Based on the results of the skin irritation study, Applied Silver is requesting waivers for eye irritation and dermal sensitization.

Guideline	Study Name	Results	Category
OCSPP 870.1100	Acute Oral Toxicity	1,098 mg/kg	3
OCSPP 870.1200	Acute Dermal Toxicity	>2000 mg/kg	3
OCSPP 870.1300	Acute Inhalation Toxicity	>0.53 mg/kg, <2.05 mg/kg	3
OCSPP 870.2400	Acute Eye Irritation	Waive	1
OCSPP 870.2500	Primary Skin Irritation	Corrosive	1
OCSPP 870.2600	Dermal Sensitization	Waive	Not a sensitizer

The resulting precautionary and first aid language is:

DANGER

Corrosive

Causes irreversible eye damage and skin burns. Harmful if absorbed through skin, swallowed or inhaled. Do not get in eyes, skin or on clothing. Avoid breathing vapor or spray mist. Wear goggles, face shield and chemical resistant clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

First Aid

If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advise.
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
If swallowed:	Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible Call a poison control center or doctor for further treatment advice.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 1, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. DAVID SWAIN
SCIENTIFIC & REGULATORY CONSULTANTS INC
APPLIED SILVER, INC.
102 1/2 CHAUNCEY STREET, PO Box 1014
COLUMBIA CITY, IN 46725-

PRODUCT NAME: SilvaClean
COMPANY NAME: APPLIED SILVER, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 90335-1
EPA RECEIPT DATE: 04/01/16

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 33, at (703) 308-8735.

Sincerely,

A handwritten signature in black ink, appearing to be "S. [unclear]".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 90335-1	2. EPA Product Manager Julie Chao	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SilvaClean	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Applied Silver, Inc. 26254 Eden Landing Road Hayward, CA 94545 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Fast Track label amendment to correct omissions from previous amendment.

No data is being submitted, therefore this is not a PRIA action. NO FEE IS REQUIRED.

Please contact David Swain @260.244.6270 or dswain@srcconsultants.com for questions.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input checked="" type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 33.8 fl. oz. (1 L), 67.6 fl. oz. (2 L)		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Swain	Title Agent for Applied Silver, Inc.	Telephone No. (Include Area Code) (260) 244-6270
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>David Swain</i>	3. Title Agent for Applied Silver, Inc.	
4. Typed Name David Swain	5. Date 3/31/2016	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 23, 2016

David Swain
Agent for Applied Silver, Inc.
Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Subject: Label Amendment – To add new textile types and revise minimum usage rate
Product Name: SilvaClean
EPA Registration Number: 90335-1
Application Date: November 10, 2015
Decision Number: 511485

Dear Mr. Swain:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling, you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

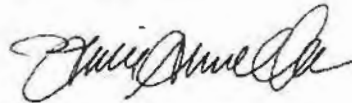
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 90335-1
Decision No. 511485

with FIFRA section 6. If you have any questions, please contact Zebora Johnson by phone at (703) 308-7080, or via email at johnson.zebora@epa.gov

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao", written in a cursive style.

Julie Chao, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Accepted Label

SilvaClean™

Antimicrobial Textile Treatment. SilvaClean™ is an antimicrobial silver treatment for commercial and industrial use on fibers or textiles SilvaClean™ is effective in inhibiting the growth of bacteria in products to which it is applied. *{These claims may appear on any label panel}*

Products containing SilvaClean™ may not make claims of antimicrobial activity other than protection of the article itself against odor-causing, staining, or deteriorating bacterial in the treated article. This product does not protect users against bacteria, viruses or other disease organisms.

SilvaClean™ is composed of:

Active Ingredient:

Silver*22.5%

Other Ingredients.....77.5%

Total.....100.0%

* from silver nitrate.

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive

See back panel for first aid and additional precautionary statements.

Net Contents: _____

EPA Reg. No. 90335-1

EPA Est. No. xxx-xx-x

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

ACCEPTED

2/23/2016

Under the Federal Insecticide, Fungicide,
and Rodenticide Act as amended, this
pesticide registered under

EPA Reg. No. 90335-1

SilvaClean™ is applied to or incorporated into industrial products listed below. For non-food contact uses only.

FOR APPLICATION IN COMMERCIAL AND INSTITUTIONAL SETTINGS

Textiles made of: cotton and cotton/polyester blend, polyester, nylon, microfiber, spandex, and nylon/spandex blend. Example items include: pillow covers; sheets; blankets; bedspreads; apparel; uniforms; jerseys; active wear; scrubs; lab coats; quilts; liners; curtains; draperies; upholstery; towels; shower curtains; and carpets.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its label.

This product is registered as a microbiostatic agent for material preservation; neither this product nor the articles treated with this product may state or imply any public health claims. Articles or substances treated with this product in accordance with the labeled directions may be exempt from FIFRA regulation pursuant to 40 CFR 152.25(a) if the intended use for incorporating this material into a treated article or substance is for the protection of the article or substance itself.

SilvaClean™ is an antimicrobial silver application that provides 0.00016% to 0.0014% (1.6 ppm – 14 ppm) silver on fibers or textiles. The treatment level of SilvaClean™ for a product will depend on the specific needs of the manufacturer, the textile being treated, and the level and type of performance desired.

Solution Preparation and Treatment: SilvaClean™ is a concentrate that must be diluted with distilled or deionized water before use. Treat textile by soaking in dilute aqueous solution and agitating for at least 2 minutes. Contact Applied Silver, Inc., for dilution and treatment instructions specific to your desired performance.

Textile must be clean prior to the application of product. Retreat textile after each laundering.

STORAGE and DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in a safe manner only in areas inaccessible to small children. Store in original container in dark location. Keep container tightly closed when not in use.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, intermediate mixtures, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA regional office for guidance.

Container Handling: Non-refillable container – do not reuse or refill this container. Return container to Applied Silver, Inc.

PRECAUTIONARY STATEMENTS AND FIRST AID

DANGER

Corrosive

Causes irreversible eye damage and skin burns. Harmful if absorbed through skin, swallowed or inhaled. Do not get in eyes, skin or on clothing. Avoid breathing vapor or spray mist. Wear goggles, face shield and chemical resistant clothing (waterproof apron, waterproof gloves covering hands, wrists, and lower forearms). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

First Aid

If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
If swallowed:	Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or when going for treatment.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters. This product is toxic to fish and aquatic invertebrates.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 17, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. DAVID SWAIN
SCIENTIFIC & REGULATORY CONSULTANTS INC
APPLIED SILVER, INC.
102 1/2 CHAUNCEY STREET, PO Box 1014
COLUMBIA CITY, IN 46725-

PRODUCT NAME: SilvaClean
COMPANY NAME: APPLIED SILVER, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 90335-1
EPA RECEIPT DATE: 11/12/15

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 33, at (703) 308-8735.

Sincerely,

A handwritten signature in black ink, appearing to be "SG" or similar, written over a horizontal line.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Scientific & Regulatory Consultants, Inc.

November 10, 2015

Ms. Julie Chao
Office of Pesticide Programs (7504P)
Document Processing Desk (AMEND)
EPA
Room S-4900, 4th Floor
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

SUBJECT: SilvaClean™
EPA Reg. No. 90335-1

Dear Ms. Chao:

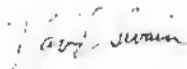
Scientific & Regulatory Consultants, Inc. is submitting a minor label amendment for SilvaClean™, EPA Reg. No. 90335-1 on behalf of Applied Silver, Inc. **No data is being submitted; therefore this is not a PRIA action. NO FEE IS REQUIRED.**

The label amendment includes the following revisions and additions:

- Addition of new textile types and example items which can be treated with this material preservative product.
- Revision of minimum usage rate

A highlighted label is attached which indicates the new claims and revised text. Five (5) clean copies of the label are also enclosed. For any questions or clarification, please contact me immediately at 260-244-6270 or dswain@srcconsultants.com.

Sincerely,



David Swain
Agent for Applied Silver, Inc.
cc: P. McCabe

SilvaClean™
EPA Reg. No. 90355-1

TRANSMITTAL DOCUMENT

1. Name and address of Submitter:

Scientific & Regulatory Consultants, Inc.
201 West Van Buren Street
Columbia City, IN 46750

AGENT FOR:
Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

2. Regulatory action in support of which this package is submitted:

Fast Track label amendment to add additional textile types and revise usage rate.

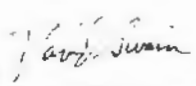
**No data is being submitted; therefore this is not a PRIA action. NO FEE IS
REQUIRED.**

3. Transmittal date:

November 10, 2015

4. Volume I Administrative Materials:

- A) Cover letter
- B) Application
- E) Label with changes and additions highlighted
- F) Five (5) "clean" copies of labeling

Company Official : David Swain 
Agent for Applied Silver, Inc.

Company Name: Applied Silver, Inc.

Company Contact: David Swain
Phone: (260) 244-6270
Fax: (260) 244-6273
dswain@srcconsultants.com



United States
Environmental Protection Agency
Washington, DC 20460



Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 90335-1	2. EPA Product Manager Julie Chao	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SilvaClean	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Applied Silver, Inc. 26254 Eden Landing Road Hayward, CA 94545 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Fast Track label amendment to add additional textile types and revise usage rate.

No data is being submitted; therefore this is not a PRIA action. NO FEE IS REQUIRED.

Section - III

1. Material This Product Will Be Packaged In:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 33.8 fl. oz. (1 L), 67.6 fl. oz. (2 L)		5. Location of Label Direction: <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product			
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name David Swain		Title Agent for Applied Silver, Inc.	
		Telephone No. (Include Area Code) (260) 244-6270	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent for Applied Silver, Inc.	
4. Typed Name David Swain		5. Date 11/10/2015	

Scientific & Regulatory Consultants, Inc.

December 30, 2014

Mr. Seiichi Murasaki
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
Room 54900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: SilvaClean™, EPA Reg. No. 90335-1

Dear Seiichi,

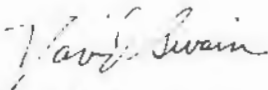
Enclosed is a final printed label (FPL) for SilvaClean™, EPA Reg. No. 90335-1. Per the Agency's June 12, 2014 registration acceptance letter, we are providing a clean copy of the label.

Enclosed:

- Cover letter
- Application Form 8570-1
- One copy of final printed label
- One copy of EPA stamped accepted label

Please contact me at (260) 244-6270 or dswain@srcconsultants.com if you have any questions.

Sincerely,



David Swain
Agent for Applied Silver Inc.

Cc: P. McCabe, Applied Silver, Inc.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 90335-1	2. EPA Product Manager Seichi Murasaki	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SilvaClean	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Applied Silver, Inc. 26254 Eden Landing Road Hayward, CA 94545 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated <u>June 12, 2014</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of one Final Printed Label, in response to Agency acceptance letter dated June 12, 2014.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	<input type="checkbox"/> Glass	
			No. per container	<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Swain	Title Agent for Applied Silver, Inc.	Telephone No. (Include Area Code) (260) 244-C273
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Applied Silver, Inc.	
4. Typed Name David Swain	5. Date 12/30/2014	

SilvaClean™

Antimicrobial Textile Treatment. SilvaClean™ is an antimicrobial silver treatment for commercial and industrial use on fibers or textiles SilvaClean™ is effective in inhibiting the growth of bacteria in products to which it is applied. *{These claims may appear on any label panel}*

Products containing SilvaClean™ may not make claims of antimicrobial activity other than protection of the article itself against odor-causing, staining, or deteriorating bacterial in the treated article. This product does not protect users against bacteria, viruses or other disease organisms.

SilvaClean™ is composed of:

Active Ingredient:

Silver*	22.5%
Other Ingredients	77.5%
Total	100.0%

* from silver nitrate.

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive

See back panel for first aid and additional precautionary statements.

Net Contents: _____

EPA Reg. No. 90335-1

EPA Est. No. xxx-xx-x

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

SilvaClean™ is applied to or incorporated into industrial products listed below. For non-food contact uses only.

FOR COMMERCIAL AND INDUSTRIAL USE ONLY. Not for Residential Use.

Textiles made of: cotton and cotton/polyester blend. Example items include: pillow covers; sheets; blankets; bedspreads; apparel; uniforms; scrubs; lab coats; quilts; curtains; draperies; upholstery; towels; and shower curtains.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its label.

This product is registered as a microbistatic agent for material preservation; neither this product nor the articles treated with this product may state or imply any public health claims.

SilvaClean™ is an antimicrobial silver application that provides 0.00013% to 0.0014% (1.3 ppm – 14 ppm) silver on fibers or textiles. The treatment level of SilvaClean™ for a product will depend on the specific needs of the manufacturer, the textile being treated, and the level and type of performance desired.

Solution Preparation and Treatment: SilvaClean™ is a concentrate that must be diluted with distilled or deionized water before use. Treat textile by soaking in dilute aqueous solution and agitating for at least 2 minutes. Contact Applied Silver, Inc., for dilution and treatment instructions specific to your desired performance.

Textile must be clean prior to the application of product.

STORAGE and DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in a safe manner only in areas inaccessible to small children. Store in original container in dark location. Keep container tightly closed when not in use.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, intermediate mixtures, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA regional office for guidance.

Container Handling: Non-refillable container – do not reuse or refill this container. Return container to Applied Silver, Inc.

PRECAUTIONARY STATEMENTS AND FIRST AID

DANGER

Corrosive

Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid breathing spray or mist. Wear goggles, face shield or safety glasses. Wear chemical-resistant apron over coveralls with long-sleeved shirt and long pants, waterproof gloves covering hands, wrists and lower forearms. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse.

First Aid

If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice.
If on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for treatment advice.
If swallowed:	Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a Poison Control Center or doctor for treatment advice.

For emergency information on SilvaClean™, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the Poison Control Center 1-800-222-1222.

Follow the manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters. This product is toxic to fish and aquatic invertebrates.



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

Reg. Number:

90335-1

Date of Issuance:

June 12, 2014

Term of Issuance:

Conditional

Name of Pesticide Product:

SilvaClean

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Comply with the Data Call-in (DCI) identified below in a timely and adequate manner and submit your responses to Product Manager 36.

GDCI-072501-1129, issued on February 29, 2012 (A copy of the DCI is available at [regulations.gov](http://www.regulations.gov), Docket ID: EPA-HQ-OPP-2009-0334 <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0334-0028>).

If you fail to satisfy the requirements in this DCI, EPA will consider appropriate regulatory action, including, among other things, cancellation under FIFRA section 6(e).

3. Submit one copy of the final printed label prior to releasing this product for sale or distribution.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

Basic CSF, dated 5/8/2014

A stamped copy of the conditionally approved label and copies of the reviews of your data submissions (DP418194 and DP418195) are enclosed for your records. If you have any questions regarding this letter, please contact Seiichi Murasaki at murasaki.seiichi@epa.gov.

Signature of Approving Official:

Seiichi Murasaki
Risk Manager (Team 33)
Regulatory Management Branch 1
Antimicrobials Division (7510P)

Date:

6/12/2014

SilvaClean™

Antimicrobial Textile Treatment. SilvaClean™ is an antimicrobial silver treatment for commercial and industrial use on fibers or textiles SilvaClean™ is effective in inhibiting the growth of bacteria in products to which it is applied. *{These claims may appear on any label panel}*

Products containing SilvaClean™ may not make claims of antimicrobial activity other than protection of the article itself against odor-causing, staining, or deteriorating bacterial in the treated article. This product does not protect users against bacteria, viruses or other disease organisms.

SilvaClean™ is composed of:

Active Ingredient:

Silver*	22.5%
Other Ingredients	77.5%
Total	100.0%

* from silver nitrate.

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive

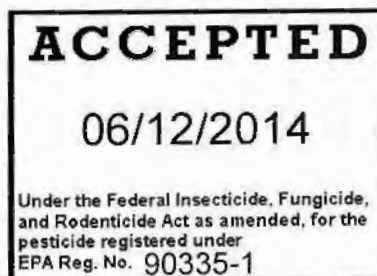
See back panel for first aid and additional precautionary statements.

Net Contents: _____

EPA Reg. No. 90335-1

EPA Est. No. xxx-xx-x

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545



SilvaClean™ is applied to or incorporated into industrial products listed below. For non-food contact uses only.

FOR COMMERCIAL AND INDUSTRIAL USE ONLY. Not for Residential Use.

Textiles made of: cotton and cotton/polyester blend. Example items include: pillow covers; sheets; blankets; bedspreads; apparel; uniforms; scrubs; lab coats; quilts; curtains; draperies; upholstery; towels; and shower curtains.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its label.

This product is registered as a microbiostatic agent for material preservation; neither this product nor the articles treated with this product may state or imply any public health claims.

SilvaClean™ is an antimicrobial silver application that provides 0.00013% to 0.0014% (1.3 ppm – 14 ppm) silver on fibers or textiles. The treatment level of SilvaClean™ for a product will depend on the specific needs of the manufacturer, the textile being treated, and the level and type of performance desired.

Solution Preparation and Treatment: SilvaClean™ is a concentrate that must be diluted with distilled or deionized water before use. Treat textile by soaking in dilute aqueous solution and agitating for at least 2 minutes. Contact Applied Silver, Inc., for dilution and treatment instructions specific to your desired performance.

Textile must be clean prior to the application of product.

STORAGE and DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in a safe manner only in areas inaccessible to small children. Store in original container in dark location. Keep container tightly closed when not in use.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, intermediate mixtures, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA regional office for guidance.

Container Handling: Non-refillable container – do not reuse or refill this container. Return container to Applied Silver, Inc.

PRECAUTIONARY STATEMENTS AND FIRST AID

DANGER

Corrosive

Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid breathing spray or mist. Wear goggles, face shield or safety glasses. Wear chemical-resistant apron over coveralls with long-sleeved shirt and long pants, waterproof gloves covering hands, wrists and lower forearms. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse.

First Aid

If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice.
If on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for treatment advice.
If swallowed:	Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a Poison Control Center or doctor for treatment advice.

For emergency information on SilvaClean™, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the Poison Control Center 1-800-222-1222.

Follow the manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters. This product is toxic to fish and aquatic invertebrates.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

Friday, April 25, 2014

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 90335-R
DP Barcode: D418195
Product Name: SilvaClean

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell, PM 33/ Seiichi Murasaki
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Applied Silver, Inc.

FORMULATION FROM LABEL:

<u>PC Code</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
72501	Silver	22.5
	<u>Other Ingredient(s):</u>	77.5
	Total:	100.0

- I BACKGROUND: Applied Silver, Inc., has submitted a set of four acute toxicity studies in support of the data requirements of their new product, "SilvaClean". The submitted label states: "SilvaClean™ is an antimicrobial silver treatment for commercial and industrial use on fiber or textiles."

There is a discrepancy between the names of the test material and the registration product. The test material is "SilvaClean Plus"; but, the registration product is "SilvaClean". The registrants' 12/20/2013 cover letter clarifies this matter: "Some studies to support SilvaClean™ were conducted under the alternate name SilvaClean™ Plus. SilvaClean™ and SilvaClean™ Plus are identical formulas." The studies were conducted by Product Safety Labs.

II RECOMMENDATIONS:

1. Each of the four submitted studies is acceptable.
2. The Chemistry and Toxicology Team (CTT) waives the requirement for the primary eye irritation study based upon the results of the primary skin irritation study. The primary skin (dermal) irritation study demonstrated the product to be corrosive to skin. As such, this product is also likely to be corrosive to eyes. CTT notes that the cover letter did not specifically ask for a waiver of the primary eye irritation study. However, it is common for registrants to ask for waivers of the eye study when the skin irritation study is assigned toxicity category I. If the registrants do not agree to have a toxicity category I for primary eye irritation, they will have to find some other means of support for this data requirement.
3. CTT waives the requirement for the dermal sensitization study for 90335-R based upon the results of the primary skin irritation study. The primary skin irritation study demonstrated the product to be corrosive to skin. The 40 CFR §158.500 states that the dermal sensitization study is "Not required if the test material is corrosive to skin or has a pH of less than 2 or greater than 11.5." Again, CTT could not find a specific request for the waiver of this study. However, it is common for registrants to ask for a waiver of the dermal sensitization study when the skin irritation study is assigned toxicity category I. If the registrants do not agree to this waiver of the dermal sensitization study, they will have to find some other means of support for this study.

The acute toxicity profile for File Symbol 90335-R is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	49270910	III	Acceptable
Acute Dermal Toxicity	49270911	III	Acceptable
Acute Inhalation Toxicity	49270912	III	Acceptable
Primary Eye Irritation	None	I	Waived
Primary Skin Irritation	49270913	I (Corrosive)	Acceptable
Dermal Sensitization	None	Nonsensitizer	Waived

III LABELING:

1. The Signal Word is "DANGER" based upon the results of the primary skin irritation study and the classification of the primary eye irritation study.
2. The Precautionary Statements must state:

"Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid breathing spray or mist. Wear goggles, face shield or safety glasses. Wear chemical-resistant apron over coveralls with long-sleeved shirt and long pants, waterproof gloves covering hands, wrists and lower forearms. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse."

The submitted label from the registrant directs users of this product to wear goggles with a face shield. The EPA does not require this; however, CTT will allow the registrants to maintain this labeling statement if they choose to do so.

3. The First Aid statement should state:

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

- Call a Poison Control Center or doctor for treatment advice.

If on Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for treatment advice.

If Inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a Poison Control Center or doctor for treatment advice.

If Swallowed:

- Call a Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a Poison Control Center or doctor.
- Do not give anything by mouth to an unconscious person.

"Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

"Have product container or label with you when calling a Poison Control Center or doctor for treatment advice."

"For emergency information on [product, use, etc.], call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222."

Statements for Contaminated Personal Protective Equipment (Label Review Manual, Chapter 10, 6, B):

“Follow the manufacturer’s instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.”

4. This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary skin irritation and the waiver of the primary eye irritation study. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.
5. Based upon data placing it in toxicity category I for primary skin irritation and the waiver of the primary eye irritation study, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP in addition to Restricted-Use Classification. CRP requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that this product be assigned Restricted-Use classification; if not, this product should at least be packaged in CRP.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Up and Down Procedure

Product Manager: 33

Reviewer: I. Blackwell

MRID No.: 49270910

Study Completion Date: 12/10/13

Lab Study No.: 37608

Testing Laboratory: Product Safety Labs

Authors: Daniel Merrill, BS, MBA

Quality Assurance (40 CFR §160.12): Included

Test Material: SilvaClean Plus, "colorless, clear liquid"

Species: Sprague-Dawley derived albino rat

Weight: 194-210 grams

Age: 9-11 weeks

Source: Harlan Laboratories, Inc.

Conclusion:

1. LD₅₀ (mg/kg):

Males= Not tested

Females= 1,098 (550-2,000)

Combined= Not tested

2. The estimated LD₅₀ is 1,098 mg/kg (550-2,000) of body weight.

3. Tox. Category: III Classification: Acceptable

Procedure (Deviations from §81-1): None

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
175	Not tested	0/1	---
550	Not tested	0/3	---
2000	Not tested	3/3	---

Observations: hypoactivity, hunched posture, irregular respiration, reduced fecal volume, soft feces, dead, euthanized.

Gross Necropsy: Lungs slightly red; stomach extremely distended or discolored; intestines moderately distended.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 33

MRID No.: 49270911

Reviewer: I. Blackwell

Study Completion Date: 12/12/2013

Lab Study No.: 37609

Testing Laboratory: Product Safety Labs

Author: Daniel Merrill, BS, MBA

Quality Assurance (40 CFR §160.12): Included

Test Material: SilvaClean Plus, "colorless, clear liquid"

Species: Sprague Dawley albino rat

Weight: Males= 227-287 g;

Age: 8-9 weeks

Females= 156-194 g

Source: Harlan Laboratories

Summary:

1. **LD₅₀ (mg/kg):**

Males > 2,000 mg/kg b.w.

Females > 2,000 mg/kg b.w.

Combined > 2,000 mg/kg b.w.

2. The estimated LD₅₀ is greater than 2,000 mg/kg of body weight.

3. **Tox. Category:** III

Classification: Acceptable

Procedure (Deviation From §81-2): None

Results:

DOSAGE (mg/kg)	Reported Mortality (NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
200	0/5	0/5	0/10
2,000	0/5	0/5	0/10

Observations: Small areas of discoloration at dose site; argyria at dose site; desquamation, small areas of superficial eschar; hyperactivity

Gross Necropsy Findings: No gross abnormalities.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: 33

MRID No.: 49270912

Reviewer: I. Blackwell

Study Completion Date: 12/12/2013

Lab Study No.: 37610

Testing Laboratory: Product Safety Labs

Author: Daniel Merrill, BS, MBA

Quality Assurance (40 CFR §160.12): Included

Test Material: SilvaClean Plus, "colorless, clear liquid"

Concentration: gravimetric= 0.53 mg/L; nominal= 7.59 mg/L

gravimetric= 2.05 mg/L; nominal= 55.37 mg/L

Species: Sprague-Dawley derived albino rat

Weight: Males= 209-250 g

Females= 155-192 g

Age: 8-9 weeks

Source: Harlan Laboratories

Summary:

1. **LC₅₀ (mg/L)**

Males	0.53 < X < 2.05 mg/L
Females	> 2.05 mg/L
Combined	0.53 < X < 2.05 mg/L
2. **The estimated LC₅₀ is (see above)**
3. **MMAD:** (See Table) μm
4. **Toxicity Category:** III **Classification:** Acceptable

Procedure (Deviation From §81-3): None

(Nose-only exposure)

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
0.53 mg/L	0/5	0/5	0/10
2.10 mg/L	3/5	1/5	4/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	Particles < 4.7 μ m
0.53 mg/L	2.6 μ m	2.245 μ m	80.75%
2.05 mg/L	2.07 μ m	2.04 μ m	89.25%

Chamber Environment		
	0.53 mg/L	2.05 mg/L
Chamber Volume	6.7 liters	28 liters
Airflow	36.0 LPM	36.0 LPM
Temperature	20° C	20-22 ° C
Relative Humidity	27-31%	34-48%

Clinical Observations: Hypoactivity, red nasal discharge, ano-genital staining, irregular respiration, ataxia.

Gross Necropsy Findings: Lungs extremely red; lungs extremely dark red and mottled; stomach and intestines extremely slightly, moderately or extremely distended.

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 33

MRID No.: 49270913

Reviewer: I. Blackwell

Study Completion Date: 12/12/2013

Lab Study No.: 37612

Testing Laboratory: Product Safety Labs

Study Director: Daniel Merrill, BS, MBA

Quality Assurance (40 CFR §160.12): Included

Test Material: SilvaClean Plus, "colorless, clear liquid"

Dosage: 0.5 mL

Species: New Zealand albino rabbit

Weight: Not reported

Age: "young adult"

Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category:** I (Corrosive)
2. **Classification:** Acceptable

Procedure (Deviations From §81-5): The lab used 3-minute, 1-hour and 4-hour exposures. The facility only exposed one test animal per each times exposure.

Procedures:

Results: Twenty-four hours after (the four hour) exposure, the single test animal displayed very slight erythema, slight edema with brown discoloration at dose site. Forty-eight hours after (four hour) exposure, the single treated subject displayed severe erythema, moderate edema, green discoloration at the dose site and corrosion.

Special Comments: Severe erythema, green discoloration and corrosion 48 hours after exposure with both the one- and four-hour treatments.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

May 20, 2014

EPA Reg#: 90335-R		DP Barcode: 418194	
		Submission #: 945337	
Product name: SilvaClean™		Registrant: Applied Silver, Inc.	
Reviewer's name: Juan F. Negrón		AD/PSB/CTT- Product Chemistry Review	
Agency due date: 06/13/2014		PSB received date: 2/24/14	
CTT received date: 2/24/14		Science received date: 2/25/14	
Formulation type: EUP		Pesticide Category:	
Integrated system: <input type="checkbox"/>	Non integrated system: <input checked="" type="checkbox"/>	Food use: <input type="checkbox"/>	Non food use: <input checked="" type="checkbox"/>
Action Code: A540		Date Completed: 05/12/14	
PC Code	CAS #	Active Ingredient Names	% wt (label)
072501	7440-22-4	Silver	22.5
Molecule structure (optional):			
Ag			
MRID(s): 49270900, 49270901 - 49270908			
Approver: Karen P. Hicks		Approved date: 05/20/14	
Guideline: 830 Group A & B			
Comments:			

M

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency


Office of Pesticide Programs

Antimicrobials Division (AD)

May 20, 2014

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 90335-R.
Product name: SilvaClean™
DP #418194

From: Juan F. Negrón, Chemist 
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)



To: Marshall Swindell / Seiichi Murasaki
PM Team 33

APPLICANT: Applied Silver, Inc.
Action code: A540
Due date: 06/13/2014

**Product Formulation
Active Ingredient**

% by wt.

Silver 22.5

BACKGROUND:

On behalf of the registrant, Applied Silver, Inc., the consultant, Scientific & Regulatory Consultants, Inc., submitted a new End-Use Product (EUP) as an integrated system. The product, SilvaClean™, is to be used to treat articles under the Treated Articles Exemption based on guidance provided in a meeting with AD staff on March 27, 2013. The product is applied to textiles (cotton and cotton/polyester blend fabrics) after each laundering to ensure and maintain effectiveness against stain-and-odor-causing bacteria. The product is an antimicrobial silver treatment for textiles for commercial and industrial use. The product is effective in inhibiting the growth of bacteria in treated articles. The Product Chemistry Reviewer has reviewed the following documents:

- A letter, dated 12/20/13. MRID # 49270900.
- A draft label, dated 12/20/13.
- Email, dated 05/09/14.
- Confidential Statements of Formula (CSFs), dated 12/20/13 & 05/08/14, for the basic and alternate (#1) formulations.
- Certificate of analysis (COA) for the raw active ingredient.
- Data matrix, dated 12/20/13.
- Transmittal document, dated 12/20/13.
- Application for pesticide registration, dated 12/20/13. Section II shows a PRIA Code A500, new use for an existing active ingredient (AI).
- Certification with respect to citation of data, dated 12/20/2013.
- Study titled "PRODUCT CHEMISTRY Discussion and Data Waivers" Volume 2 MRID # 49270901.
- Study titled "Product Chemistry Identity, Composition and Analysis" Volume 3 MRID # 49270902.
- Study titled "SilvaClean™ Plus: Preliminary Analysis - Silver" Volume 4 MRID # 49270903.
- Study titled "SilvaClean™ Plus: Preliminary Analysis – Silver" Volume 5 MRID # 49270904.
- Study titled "SilvaClean™ Plus Preliminary Analysis, Impurities Only" Volume 6 MRID # 49270905.
- Study titled "SilvaClean™ Plus Preliminary Analysis, Impurity Only" Volume 7 MRID # 49270906.
- Study titled "SilvaClean™ Plus: Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscosity, and Density/Relative Density" Volume 8 MRID # 49270907.
- Study titled "SilvaClean™ Plus: 14-Day Combined Accelerated Storage Stability and Corrosion Characteristics Study" Volume 9 MRID # 49270908.

FINDINGS:

1. The CSFs, dated 12/20/13, for the basic and alternate (#1) formulations are obsolete. The registrant decided to eliminate alternate #1 formulation by including the supplier for the AI as part of the basic formulation.
2. The CSF, dated 05/08/14, for the basic formulation is revised.
3. The CSF and the label have the same nominal concentration for the AI.

4. All components meet the EPA Standard Certified Limits.
5. The registrant conducted five batches of analysis. The result of those assays are as follows:

Sample (Lot #) MRID #49270903	% Ag	Avg % Ag	Sample (Lot #) MRID #49270904	% Ag	Avg % Ag
AMG-0006-2	20.4	21.1	AA-0008-4	22.4	22.4
	21.1			22.2	
	21.1			22.4	
AMG-0006-3	21.5	21.8	AA-0001-1	23.4	23.3
	21.7			23.5	
	22.1			22.9	
AMG-0013-1 3	23.2	23.5	AA-0003-1	21.9	21.8
	23.5			21.7	
	23.7			21.9	
AMG-0014-1	22.2	22.6	AA-0008-1	22.2	21.9
	22.7			22.1	
	22.8			21.5	
AMG-0015-1 3	23.2	23.4	AA-0008-3	22.4	22.6
	23.2			22.9	
	23.8			22.3	
Completed on 12/13/13 for silvaClean Plus			Completed on 12/13/13 for silvaClean Plus		

Five lots of the test substance, identified as SilvaClean™ Plus, were received on October 24, 2013
MRID #49270903 (See MRID # 49270906 for impurities)

Lot #	PSL Reference Number
AMG-0006-2	131024-14G
AMG-0006-3	131025-15G
AMG-0013-1	131024-16G
AMG-0014-1	131024-17G
AMG-0015-1	131024-18G

MRID #49270904 (See MRID # 49270905 for impurities)

Lot #	PSL Reference Number
AA-0008-4	131024-3G
AA-0001-1	131025-4G
AA-0003-1	131024-5G
AA-0008-1	131024-6G
AA-0008-3	131024-7G

The registrant conducted a preliminary analysis for impurities (see MRID # 49270905). In this study the limit of quantification (LOQ) and the limit of detection (LOD) have been reported along with the linearity. The laboratory conducted the assay using the lot # shown on MRID # 49270904. The laboratory proceeded for determination of impurities by inductively coupled plasma/mass spectrometry (ICP/MS) for sodium, zinc, nickel, & lead (see MRID #49270905 & 49270906). The study was completed on 12/18/13. The LOQ for impurities are shown to be 0.005 ug/ml except for lead which is 0.001 ug/ml

6. The registrant conducted an accelerated storage stability study for (0, & 14) days @ 40°C ($\pm 2^{\circ}\text{C}$) and the results are as follows: (Study titled "SilvaClean™ Plus: 14-Day Combined Accelerated Storage Stability and Corrosion Characteristics Study" Volume 9 MRID # 49270908)

SilvaClean™ Plus, Concentration Ag = 22.5 Accelerated storage stability @ 54°C $\pm 2^{\circ}\text{C}$				
Sample ID	Rep	% Ag	Average (%)	Days
Lot #: AA-0008-4	1	22.4	22.4	0
	2	22.2		
	3	23.0		
	4	22.2		
	5	22.4		
	1	22.3	22.2	14
	2	22.4		
	3	21.9		

Results of the assay meet the EPA Standard Certified Limits.

7. The Corrosion characteristic study reveals that the container (test system) in this study was lime-green high density polyethylene with a spray cap apparatus. The test substance remained essentially unchanged in appearance from baseline.

CONCLUSIONS:

The CSF, dated 5/08/14, for the basic formulation is acceptable. The registrant decided to update the CSF showing one CSF. The registrant realized that there was no need to request wider certified limits since data shows not to support wider certified limits. Therefore, the registrant decided to use the EPA Standard Certified Limits. The OPPTS 830 Group (A & B) guidelines for product chemistry data requirements applicable to end-use products have been met.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system ☐
- Are all TGAIs used registered? Yes ☐ No ☐
- Integrated formulation system ☒
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inert ingredients for non-food use:

Yes ☒ No ☐ NA ☐

c. Physical state of product: Liquid.

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes ☒ No ☐

e. The NCs and CLs are acceptable.

Yes ☒ No ☐

f. Active ingredients

<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
------------------	-------------------	-------------------

Silver	22.5	21.8	23.2
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- Do all impurities of toxicological significance have a UCL?
Yes ☐ No ☐ Not applicable ☒
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes ☐ No ☐ Not applicable ☒

II PRODUCT LABEL

- a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐
- b. The formula contains one of the following:
- | | | |
|--|------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • 1.0% or more of methyl alcohol: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • sodium nitrite at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • a toxic List 1 inert at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • arsenic in any form: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
- c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒
- d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label. Yes ☐ No ☐ Not applicable ☒
- e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses. Yes ☐ No ☐
- f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information). Yes ☒ No ☐

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity	A	49270902
830.1600 Description of Materials	A	49270902
830.1620 Production Process	A	49270902
830.1650 Formulation Process	A	49270902
830.1670 Formation of Impurities	A No new chemical entities are created during the manufacture of SilvaClean™. Therefore, no new impurities are formed in the manufacturing process.	49270902
830.1700 Preliminary Analysis	A	49270903, 49270904
830.1750 Certified Limits	See CSF	49270902
830.1800 Enforcement Analytical Method	A Atomic absorption spectrophotometry	49270902
830.1900 Submittal of Samples	A Available upon request. (see email dated 05/08/14)	

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR=not required); G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

Table B:**Physical and Chemical Characteristics (Series 830, Group B)**

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	[Not required for end-use products.] However, the registrant indicated that it is colorless @ 20 °C.	49270901, 49270907
830.6303 Physical State	A	Clear Liquid @ 20 °C.	49270903, 49270907
830.6304 Odor	NR	[Not required for end-use products.] However, the registrant indicated that it is odorless @ 20°C.	49270907
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	[Not required for end-use products.]	49270901
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	However, the registrant indicated that it is: Compatible in water, 10% mono-ammonium phosphate, iron powder, & Kerosene, except 10% potassium permanganate.	49270907
830.6315 Flammability/ Flame Extension	A	Contains no flammable ingredients.	49270901
830.6316 Explodability	A	Contains no explosive ingredients.	49270901
830.6317 Storage Stability	A	The registrant conducted an accelerated storage stability study for (0, & 14) days. The sample was stored at room temperature in the absence of light. Two sample were stored @ 54 °C ± 2 °C. Vol 9	49270908
830.6319 Miscibility	A	Not an emulsifiable liquid for dilution with petroleum solvents.	49270901
830.6320 Corrosion Characteristics	A	The registrant conducted an accelerated storage stability study for (0, 15, 30, & 45) days. The container of the product was solid brown high-density polyethylene (HDPE). Vol 9	49270908
830.6321 Dielectric Breakdown Voltage	A	Not to be used in/on/around electrical equipment.	49270901
830.7000 pH ²	A	1% soln, the pH is 5.77 ± 0.01 @ 20°C	49270907
830.7050 UV/Visible Absorption	NR	[Not required for end-use products.]	49270901
830.7100 Viscosity	A	0.9 cSt/s ± 0.004 @ 20°C; 0.6 cSt/s ± 0.001 @ 40°C	49270907
830.7200 Melting Point/Melting Range	NR	[Not required for end-use products.]	49270901

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7220 Boiling Point/Boiling Range	NR	<i>[Not required for end-use products.]</i>	49270901
830.7300 Density/Relative Density/Bulk Density	A	1.402 g/ml @ 20°C	49270907
830.7370 Dissociation Constants in Water	NR	<i>[Not required for end-use products.]</i>	49270901
830.7520 Particle size, fiber length, & diameter distribution	A	SilvaClean™ contains 22.5% silver from 35.4% silver nitrate. Applied Silver was directed by EPA to test particle size for a metallic silver product by comparing filtration results to a control, specifically silver nitrate. (Dr. Jed Costanza, teleconference, May 9, 2013 and confirming emails from July, 2013) Thus, particle size data is not needed since it is well known that silver nitrate produces ionic silver with a particle size of < 1nm.	49270901
830.7550/830.7560/830.7570 Partition Coefficient	NR	<i>[Not required for end-use products.]</i>	49270901
830.7840/830.7860 Water Solubility	NR	<i>[Not required for end-use products.]</i>	49270901
830.7950 Vapor Pressure	NR	<i>[Not required for end-use products.]</i>	49270901

A=acceptable; N=not acceptable; NA=technically not applicable; NR=not required); G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

Table B: Data Waiver Requests for Silver TGAI for Silver RED based on information provided in the 1992 Silver RED and 40 CFR Part 158W.

Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color		<i>Metallic</i>	49270901
830.6303 Physical State		Solid	49270901
830.6304 Odor		<i>None</i>	49270901
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions		Stable to sunlight and metal/metal ions.	49270901
830.6314 Oxidation/ Reduction; Chemical Incompatibility			49270901
830.6315 Flammability/ Flame Extension		Not required for TGAI	49270901
830.6316 Explodability		Not required for TGAI	49270901
830.6317 Storage Stability		Not required for TGAI	49270901
830.6319 Miscibility		Not required for TGAI	49270901
830.6320 Corrosion Characteristics		Not required for TGAI	49270901
830.6321 Dielectric Breakdown Voltage		Not required for TGAI	49270901
830.7000 pH ²		NA	49270901
830.7050 UV/Visible Absorption		NA	49270901
830.7100 Viscosity		Not required for TGAI	49270901
830.7200 Melting Point/Melting Range		960.5 °C	49270901
830.7220 Boiling Point/Boiling Range		2000 °C	49270901
830.7300 Density/Relative Density/Bulk Density		10.49 g/mL at 15° C	49270901
830.7370 Dissociation Constants in Water			49270901
830.7520 Particle size, fiber length, & diameter distribution			
830.7550/830.7560/830.7570 Partition Coefficient			
830.7840/830.7860 Water Solubility		Not soluble in water.	49270901
830.7950 Vapor Pressure		NA	49270901

A=acceptable; N=not acceptable; NA=technically not applicable; NR=not required); G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

Negron, Juan

From: dswain@srcconsultants.com
Sent: Thursday, May 08, 2014 11:40 AM
To: Negron, Juan
Subject: SilvaClean (EPA Reg. No. 90335-R)

Good morning Juan,

Thank you for your call.

In support of SilvaClean (EPA Reg. No. 90335-R) by Applied Silver, Inc.

For OPPTS Guideline 830.1900 – Submittal of Samples.

“Samples available upon request.”

Please send the CSF template in Word Version.

Thanks for your help.

Best regards,

David

David Swain

Scientific & Regulatory Consultants, Inc.
P.O. Box 1014 | Columbia City, IN 46725
260.244.6270 | www.srcconsultants.com

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information that is exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

Negron, Juan

From: dswain@srcconsultants.com
Sent: Friday, May 09, 2014 3:07 PM
To: Negron, Juan
Subject: RE: SilvaClean (EPA Reg. No. 90335-R)
Attachments: CSF_basic formula SilvaClean 050814.pdf; CoA Alfa Aesar AA-0001.pdf; CoA AMG-0006.pdf

Hi Juan,

Please find attached the revised CSF for SilvaClean, 90335-R. I believe I have revised all the items we talked about.

I have also attached a COA from both suppliers. I wasn't sure which supplier you needed so I am sending both.

Finally, as we spoke about, one of the values for the Preliminary Analysis study Volume 5, MRID 49270904 for lot AA-0001-1 was 23.3%. This is slightly higher than the upper certified limit in box 14a of (23.2%). Let me know if you want me to revise this box to say 23.3% to account for that one result.

Let me know if you have any questions. Have a great weekend.

Best regards,

David

David M. Swain
Scientific & Regulatory Consultants, Inc.
Phone: 260-244-6270

From: Negron, Juan [mailto:Negron.Juan@epa.gov]
Sent: Thursday, May 08, 2014 3:10 PM
To: dswain@srcconsultants.com
Subject: RE: SilvaClean (EPA Reg. No. 90335-R)

FYI

From: dswain@srcconsultants.com [mailto:dswain@srcconsultants.com]
Sent: Thursday, May 08, 2014 11:40 AM
To: Negron, Juan
Subject: SilvaClean (EPA Reg. No. 90335-R)

Good morning Juan,

Thank you for your call.

In support of SilvaClean (EPA Reg. No. 90335-R) by Applied Silver, Inc.

For OPPTS Guideline 830.1900 – Submittal of Samples.

"Samples available upon request."

Please send the CSF template in Word Version.

Thanks for your help.

Best regards,

David

David Swain

Scientific & Regulatory Consultants, Inc.

P.O. Box 1014 | Columbia City, IN 46725

260.244.6270 | www.srcconsultants.com

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PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12-23-13
 Experts In-Processing Signature: B.B. Date 12-30-13 Fee Paid: Yes ☒
 Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>90335-R</u>		EPA Receipt Date: <u>12-23-13</u>								
Items for Review				Yes	No	N/A*				
1	Application Form (EPA Form 8570-1) signed & complete including package type			X						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X						
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no									
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X						
	Certificate and data matrix consistent			X						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no									
	If applicable, is there a letter of Authorization for exclusive use only.									
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X				
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X						
5	a) Selective Method (Fee category experts use)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td style="text-align: center;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no									
X										
	b) Cite-All (Fee category experts use)									
	c) Applicant owns all data (Fee category experts use)									
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X						
7	Is the data package consistent with PR Notice 86-5			X						
8	Notice of Filing included with petitions					X				

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			
<p>Comments: Studies passed 11-3 review. Pass 492709 4-sub.</p> <p>Active ingredient and water only, no inerts to review.</p> <p style="text-align: right;">TJ</p>				

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 30, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-486319
EPA File Symbol or Registration Number: 90335-R
Product Name: SilvaClean
EPA Receipt Date: 23-Dec-2013
EPA Company Number: 90335
Company Name: APPLIED SILVER, INC

SALLY HAYES
SCIENTIFIC & REGULATORY CONSULTANTS INC
APPLIED SILVER, INC
PO Box 1014
COLUMBIA CITY, IN 46725-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

No additional payment is due at this time. Unless it becomes necessary to revise the PRIA code assigned to this action, we will process a refund of your \$7,293 overpayment after processing has been completed.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

A handwritten signature in cursive script, appearing to read "Teresa Downe".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{9453379~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☒ AD

☐ BPPD

☐ RD

Risk Mgr. 33

Receipt No.

S-

945337

EPA File Symbol/Reg. No.

90335-R

Pin-Punch Date:

12/23/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

~~A540~~ A500

Granted:

A540

Amount Due: \$ 4863

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: team 4

Date: 12/26/13

Remarks:

Registrant submitted A500 Paid \$12,156. HOWEVER this PEA should be an A540 because, active! Silver (Silver nitrate) is already registered for textile, fiber uses.
*(Needs to be Recoded)

S: 945337

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Print Letter

Application Type: New Registration

Billable: ☒ Yes ☐ No

Enter More Information

Company: 90335 APPLIED SILVER, INC



Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 90335-R Product Name: SilvaClean

Override#

Me Too

Me Too

Section3:

Product Name:

Application Date: 20-Dec-2013



OPP Rec'd Date: 23-Dec-2013



Front End Date: 23-Dec-2013



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

Receipt Content

Study

CSF

OPP Target Date:

View/Edit

Fast Track: ☐New Ingredient: ☐

Receipt Description:

E-submission # 5171. Application for pesticide registration.

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Subject:

FW: Pay.gov Payment Confirmation: PRIA Service Fees

----- Forwarded message -----

From: <paygovadmin@mail.doc.twai.gov>

Date: Tue, Dec 17, 2013 at 3:24 PM

Subject: Pay.gov Payment Confirmation: PRIA Service Fees

To: "paul@appliedsilver.com" <paul@appliedsilver.com>

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@cleve.frb.org.

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 25DJ605D

Agency Tracking ID: 74544537774

Account Holder Name: Applied Silver LLC

Transaction Type: ACH Debit

Transaction Amount: \$12,156.00

Payment Date: Dec 18, 2013

Account Type: Business Checking

Routing Number: 122000247

Account Number: *****8322

Transaction Date: Dec 17, 2013 6:24:25 PM

Total Payments Scheduled: 1

Frequency: OneTime

Decision Number:

Registration Number:

Company Name: Applied Silver, Inc.

Company Number: 90335

Action Code: A500

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

--
CONFIDENTIALITY WARNING: The contents of this e-mail and any attachment are the property of Applied Silver, Inc., and are intended for the addressee only. Any reader of this message who is not the intended recipient or the employee or agent responsible to deliver to the intended recipient, is notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you receive this communication in error please notify us immediately and delete all copies from your computer system



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 90335-x	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SilvaClean	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Applied Silver, Inc. 26254 Eden Landing Road Hayward, CA 94545 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. See explanation and cover letter Product Name

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Initial Registration in support of SilvaClean, for application to cotton and cotton/polyester blend fabrics under the Treated Articles Exemption. PRIA Code A500, new use for an existing active ingredient. Proof of PRIA payment attached.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input checked="" type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt.		No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 33.8 fl. oz. (1 L), 67.6 fl. oz. (2 L)		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Sally Hayes		Title Agent for Applied Silver, Inc.		Telephone No. (Include Area Code) (260) 244-6270	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent for Applied Silver, Inc.			
4. Typed Name Sally Hayes		5. Date 12/20/2013			

Scientific & Regulatory Consultants, Inc.

December 20, 2013

Mr. Marshall Swindell
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: SilvaClean™, EPA Reg. No. 90335-x

Dear Marshall,

Enclosed is an application for the registration of SilvaClean™. SilvaClean™ contains the unregistered active silver from silver nitrate and will be used to treat articles under the Treated Articles Exemption based on guidance provided in a meeting with AD staff on March 27, 2013 and subsequent teleconference on April 29, 2013. SilvaClean™ is applied to textiles after each laundering to ensure and maintain effectiveness against stain-and odor-causing bacteria.

This is a new registration and the first registration for Applied Silver, Inc. (Applied Silver). We are submitting under the PRIA action code A500 with a PRIA fee of \$12,156 and a 9 month review time. A copy of the payment confirmation via www.pay.gov is attached.

Efficacy

SilvaClean™ is used to treat textiles under the Treated Articles Exemption. EPA does not require submission of non-public health efficacy data.

Product Chemistry / Confidential Statement of Formula

The inert ingredient(s) used in SilvaClean™ are on EPA's inert list.

The active ingredient, silver from silver nitrate, is not registered. The preliminary analysis of five lots for each supplier is provided along with these additional studies:

- OCSP 830.1700 Preliminary Analysis – Silver (Lab Study 37621), MRID 49270903 (Volume 4)
- OCSP 830.1700 Preliminary Analysis – Silver (Lab Study 37606), MRID 49270904 (Volume 5)
- OCSP 830.1700 Preliminary Analysis – Impurities (Lab Study 37607), MRID 49270905 (Volume 6)
- OCSP 830.1700 Preliminary Analysis – Impurities (Lab Study 37622), MRID 49270906 (Volume 7)
- OCSP 830.1550-7950 Product Chemistry Discussion and Data Waivers, MRID 49270901 (Volume 2)
- OCSP 830.1550-1800 Product Identity, Composition, and Analysis, MRID 49270902 (Volume 3)
- OCSP 830.6302-7300 Physical and Chemical Characteristics, MRID 49270907 (Volume 8)

P.O. Box 1014
Columbia City, IN 46725

www.srconsultants.com

P: 260.244.6270
F: 260.244.6273

- OCSSP 830.6317, 6320 Accelerated Storage Stability, Corrosion Characteristics, MRID 49270908 (Volume 9)

Applied Silver, Inc. requests a broader range for the active ingredient than those provided in 40 CFR 158.175(b)(2). The justification for the expanded ranges is in MRID 49270902 (Volume 3, Product Identity, Composition and Analysis).

Waiver requests for SilvaClean™ and silver are in MRID 49270901 (Volume 2, Product Chemistry Discussion and Data Waivers).

Acute Toxicity

The acute toxicity for SilvaClean™ is supported through acute toxicity studies and data waivers. These, along with information on the unregistered active silver, are found in:

- OCSP 870.1100 – 7800 Toxicity Discussion and Data Waivers, MRID 49270909 (Volume 10)
- OCSP 870.1100 Acute Oral Toxicity, MRID 49270910 (Volume 11)
- OCSP 870.1200 Acute Dermal Toxicity, MRID 49270911 (Volume 12)
- OCSP 870.1300 Acute Inhalation Toxicity, MRID 49270912 (Volume 13)
- OCSP 870.2500 Acute Dermal Irritation, MRID 49270913 (Volume 14)

Other Studies

SilvaClean™ is intended for repeated application. Textile uptake studies were conducted that demonstrate SilvaClean™ treated textile remains in an Operating Range¹ that ensures the product is efficacious but does not exceed levels of toxicological concerns. This study is assigned MRID 49270915 (Volume 16).

Information for Post Applicator Exposure (MRID 49270914, Volume 15) and the method of support for Environmental Fate (MRID 49270916, Volume 17) are provided.

Alternate Test Material Names

Some studies to support SilvaClean™ were conducted under the alternate name SilvaClean™ Plus. SilvaClean™ and SilvaClean™ Plus are identical formulas.

Labeling/Label Claims

SilvaClean™ is an antimicrobial silver treatment for textiles for commercial and industrial use. SilvaClean™ is effective in inhibiting the growth of bacteria in treated articles. SilvaClean™ is used for repeated treatment of textiles under the Treated Articles exemption.

¹ Operating Range – The ppm silver in textile above efficacious levels and below levels of toxicological concern.

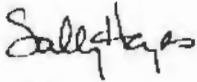
Scientific & Regulatory Consultants, Inc.

Products containing SilvaClean™ may not make claims of antimicrobial activity other than protection of the article itself against odor-causing, staining, or deteriorating bacterial growth in the treated article. This product does not protect users against bacteria, viruses or other disease organisms.

We ask the Agency to consider the alternate Container Handling text provided on the proposed label. Applied Silver will ask users to return empty containers, such that they can be appropriately processed.

Please contact me at (260) 244-6270 or shayes@srcconsultants.com if you have any questions regarding this submission.

Regards,



Sally Hayes
Agent for Applied Silver Inc.

Cc: P. McCabe, Applied Silver, Inc.

TRANSMITTAL DOCUMENT
SilvaClean™
EPA Reg. No. 90335-X

Name and Address of Submitter: Scientific & Regulatory Consultants, Inc.
 PO Box 1014
 Columbia City, IN 46725

Agent for: Applied Silver, Inc.
 26254 Eden Landing Road
 Hayward, CA 94545

Regulatory action in support of which this package is submitted: PRIA Action A500, PRIA fee \$12,156

Transmittal Date: December 20, 2013

Volume No.	Administrative Materials
	Transmittal Document
	Cover Letter
	Copy of Agent Authorization
	Copy of PRIA payment (\$12,156 for A500 Initial Registration)
1	EPA Form 8570-1 Application for Pesticide Registration
	EPA Form 8570-34 Certification with Respect to Citation of Data (EP)
	EPA Form 8570-34 Certification with Respect to Citation of Data (TGAI)
	EPA Form 8570-35 Data Matrix (EP)
	EPA Form 8570-35 Data Matrix (TGAI)
	EPA Form 8570-4 Confidential Statement of Formula (basic and one (1) alternate)
	Product Label

Volume No.	Citation	MRID No.
2	OCSPP 830.1550-7950 Product Chemistry Discussion and Data Waivers	<u>49270901</u>
3	OCSPP 830.1550-1800 Product Identity, Composition, and Analysis	<u>49270902</u>
4	OCSPP 830.1700 Preliminary Analysis - Silver (Lab Study 37621)	<u>49270903</u>
5	OCSPP 830.1700 Preliminary Analysis - Silver (Lab Study 37606)	<u>49270904</u>
6	OCSPP 830.1700 Preliminary Analysis - Impurities (Lab Study 37607)	<u>49270905</u>
7	OCSPP 830.1700 Preliminary Analysis - Impurities (Lab Study 37622)	<u>49270906</u>
8	OCSPP 830.6302-7300 Physical and Chemical Characteristics (Lab Study 37615)	<u>49270907</u>
9	OCSPP 830.6317 & 830.6320 Accelerated Storage Stability and Corrosion Characteristics (Lab Study 37614)	<u>49270908</u>
10	OCSPP 870.1100-7800 & 875.1100-1700 Toxicity Discussion and Waiver requests	<u>49270909</u>
11	OCSPP 870.1100 Acute Oral Toxicity (Lab Study 37608)	<u>49270910</u>

12	OCSP 870.1200 Acute Dermal Toxicity (Lab Study 37609)	<u>49270911</u>
13	OCSP 870.1300 Acute Inhalation Toxicity (Lab Study 37610)	<u>49270912</u>
14	OCSP 870.2500 Acute Dermal Irritation (Lab Study 37612)	<u>49270913</u>
15	OCSP 875.1700-2900 Applicator Exposure and Post Application Exposure	<u>49270914</u>
16	Silver Uptake in Textile	<u>49270915</u>
17	OCSP 835 & 850 Series: Non-Target Organisms and Plants and Environmental Fate	<u>49270916</u>

Company Official: Sally Hayes, Agent
Company Name: Scientific & Regulatory Consultants, Inc.
Company Contact: Phone: 260-244-6270
Email: shayes@srcconsultants.com



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1200 Pennsylvania Avenue, N.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Applied Silver, Inc. 26254 Eden Landing Road, Hayward, CA 94545	EPA Registration Number/File Symbol 90335-x
Active Ingredient(s) and/or representative test compound(s) Silver (EP)	Date December 20, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) application to fabrics (treated articles exemption); bacteriostat	Product Name SilvaClean™

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Sally Hayes

Date

12/20/2013

Typed or Printed Name and Title

Sally Hayes, Agent

A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAi in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAi)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAi Data Submitted
830.1550	Product Identity & Composition	✓		
830.1600	Description of materials used to produce the product	✓		
830.1650	Description of formulation process	✓		
830.1670	Discussion on the formation of impurities	✓		
830.1700	Preliminary analysis	✓		
830.1750	Certified limits (158.345)	✓		
830.1800	Enforcement analytical method	✓		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAi Data Submitted
830.6302	Color	✓		
830.6303	Physical State	✓		
830.6304	Odor	✓		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓		
830.6315	Flammability	✓		
830.6316	Explosibility	✓		
830.6317	Storage stability*	✓		
830.6319	Miscibility	✓		
830.6320	Corrosion Characteristics*	✓		
830.6321	Dielectric Breakdown Voltage	✓		
830.7000	pH	✓		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	✓		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	✓		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required

*May not be included with initial application

A540 – Acute Toxicity Requirements

New products must either:

- 1) supply the product specific acute toxicity 6 pack data (listed below),
- 2) provide a bridging rationale document or waiver request or,
- 3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)		✓		
830.1200	Acute Dermal (LD50)		✓		
830.1300	Acute Inhalation (LC50)		✓		
830.2400	Acute Eye Irritation		✓		
830.2500	Acute Dermal Irritation		✓		
830.2600	Dermal Sensitization		✓		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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DATA MATRIX

Date: December 20, 2013			EPA Reg No./File Symbol: 90335-X		Page 1 of 4
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545			Product SilvaClean™		
Ingredient: Silver (EP)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<i>Product Chemistry</i>					
OCSPP 830.1550	Product Identity and Composition	49270902	Applied Silver, Inc.	OWN	
OCSPP 830.1600	Description of Materials Used to Produce the Product	49270902	Applied Silver, Inc.	OWN	
OCSPP 830.1620	Description of Production Process	49270902	Applied Silver, Inc.	OWN	
OCSPP 830.1650	Description of Formulation Process	49270902	Applied Silver, Inc.	OWN	
OCSPP 830.1670	Discussion of Formation of Impurities	49270902	Applied Silver, Inc.	OWN	
OCSPP 830.1700	Preliminary Analysis - Silver	49270903	Applied Silver, Inc.	OWN	
OCSPP 830.1700	Preliminary Analysis - Silver	49270904	Applied Silver, Inc.	OWN	
OCSPP 830.1700	Preliminary Analysis - Impurities	49270905	Applied Silver, Inc.	OWN	
OCSPP 830.1700	Preliminary Analysis - Impurities	49270906	Applied Silver, Inc.	OWN	
OCSPP 830.1750	Certified Limits	49270902	Applied Silver, Inc.	OWN	
OCSPP 830.1800	Enforcement Analytical Method	49270902	Applied Silver, Inc.	OWN	
OCSPP 830.6302	Color	49270907	Applied Silver, Inc.	OWN	
Signature <i>Sally Hayes</i>			Name and Title Sally Hayes, Agent		Date 12/20/2013



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DATA MATRIX

Date: December 20, 2013			EPA Reg No./File Symbol: 90335-X		Page 1 of 4
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545			Product SilvaClean™		
Ingredient: Silver (EP)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
Signature <i>Sally Hayes</i>			Name and Title Sally Hayes, Agent		Date 12/20/2013



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DATA MATRIX

Date: December 20, 2013			EPA Reg No./File Symbol: 90335-X		Page 2 of 4
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545			Product SilvaClean™		
Ingredient: Silver (EP)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OCSPP 830.6303	Physical State	49270907	Applied Silver, Inc.	OWN	
OCSPP 830.6304	Odor	49270907	Applied Silver, Inc.	OWN	
OCSPP 830.6313	Stability to normal and elevated temps, metals, ions	49270901	Applied Silver, Inc.	OWN	¹
OCSPP 830.6314	Oxidation/Reduction: chemical incompatibility	49270907	Applied Silver, Inc.	OWN	
OCSPP 830.6315	Flammability	49270901	Applied Silver, Inc.	OWN	²
OCSPP 830.6316	Explosibility	49270901	Applied Silver, Inc.	OWN	³
OCSPP 830.6317	Storage Stability	49270908	Applied Silver, Inc.	OWN	
OCSPP 830.6319	Miscibility	49270901	Applied Silver, Inc.	OWN	⁴
OCSPP 830.6320	Corrosion Characteristics	49270908	Applied Silver, Inc.	OWN	
OCSPP 830.6321	Dielectric Breakdown Voltage	49270901	Applied Silver, Inc.	OWN	⁵
OCSPP 830.7000	pH	49270907	Applied Silver, Inc.	OWN	
OCSPP 830.7100	Viscosity	49270907	Applied Silver, Inc.	OWN	
Signature <i>Sally Hayes</i>			Name and Title Sally Hayes, Agent		Date 12/20/2013

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¹ N/A: Product is an EP

² N/A: Product contains no flammable ingredients.

³ N/A: Product contains no explosive ingredients.

⁴ N/A: Product is not an emulsifiable liquid to be diluted with petroleum solvents.

⁵ N/A: Product is not for use in/on/around electrical equipment

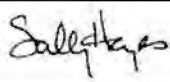


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DATA MATRIX

Date: December 20, 2013			EPA Reg No./File Symbol: 90335-X		Page 2 of 4
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545			Product SilvaClean™		
Ingredient: Silver (EP)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	1
			Applied Silver, Inc.	OWN	2
			Applied Silver, Inc.	OWN	3
			Applied Silver, Inc.	OWN	4
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	5
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	6
			Applied Silver, Inc.	OWN	
Signature 			Name and Title Sally Hayes, Agent		Date 12/20/2013

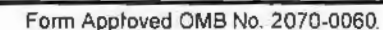


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DATA MATRIX

Date: December 20, 2013			EPA Reg No./File Symbol: 90335-X		Page 3 of 4
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545			Product SilvaClean™		
Ingredient: Silver (EP)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OCSPP 830.7200	Melting Point/Melting Range	49270901	Applied Silver, Inc.	OWN	1
OCSPP 830.7220	Boiling Point/Boiling Range	49270901	Applied Silver, Inc.	OWN	1
OCSPP 830.7300	Density / Relative Density / Bulk Density	49270907	Applied Silver, Inc.	OWN	
OCSPP 830.7370	Dissociation Constant	49270901	Applied Silver, Inc.	OWN	1
OCSPP 830.7520	Particle Size, Fiber Strength, Diameter Distribution	49270901	Applied Silver, Inc.	OWN	
OCSPP 830.7550	Particle Coefficient (n-Oct/H ₂ O) shake flask	49270901	Applied Silver, Inc.	OWN	1
OCSPP 830.7560	Particle Coefficient (n-Oct/H ₂ O) generator column	49270901	Applied Silver, Inc.	OWN	1
OCSPP 830.7570	Particle Coefficient (n-Oct/H ₂ O) estimation by liquid	49270901	Applied Silver, Inc.	OWN	1
OCSPP 830.7840	Water Solubility: column elution/shake flask method	49270901	Applied Silver, Inc.	OWN	1
OCSPP 830.7860	Water Solubility: generator column method	49270901	Applied Silver, Inc.	OWN	1
OCSPP 830.7950	Vapor Pressure	49270901	Applied Silver, Inc.	OWN	1
OCSPP 830 Series	Product Chemistry Discussion and Data Waivers	49270901	Applied Silver, Inc.	OWN	
Signature <i>Sally Hayes</i>			Name and Title Sally Hayes, Agent		Date 12/20/2013



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DATA MATRIX

Date: December 20, 2013

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Applicant's/Registrant's Name & Address

Product

Applied Silver Inc.

SilvaClean™

28254 Eden Landing Road
Hayward, CA 94545

Ingredient: Silver (EP)

Signature		Name and Title	Date
		Sally Hayes, Agent	12/20/2013



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DATA MATRIX

Date: December 20, 2013			EPA Reg No./File Symbol: 90335-X		Page 4 of 4
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545			Product SilvaClean™		
Ingredient: Silver (EP)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<i>Acute Toxicity</i>					
OCSP 870.1100	Acute Oral Toxicity	49270910	Applied Silver, Inc.	OWN	
OCSP 870.1200	Acute Dermal Toxicity	49270911	Applied Silver, Inc.	OWN	
OCSP 870.1300	Acute Inhalation Toxicity	49270912	Applied Silver, Inc.	OWN	
OCSP 870.2400	Acute Eye Irritation	49270909	Applied Silver, Inc.	OWN	
OCSP 870.2500	Primary Skin Irritation	49270913	Applied Silver, Inc.	OWN	
OCSP 870.2600	Skin Sensitization	49270909	Applied Silver, Inc.	OWN	
OCSP 870 Series	Toxicity Discussion and Waiver requests	49270909	Applied Silver, Inc.	OWN	
(no guideline)	Silver Uptake in Textile	49270915	Applied Silver, Inc.	OWN	
Signature	Sally Hayes		Name and Title		Date
			Sally Hayes, Agent		12/20/2013



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Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	

Ingredient: Silver (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	
			Applied Silver, Inc.	OWN	

Signature 	Name and Title Sally Hayes, Agent	Date 12/20/2013
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Date: December 20, 2013			EPA Reg No./File Symbol: 90335-X		Page 1 of 6
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545			Product SilvaClean™		
Ingredient: Silver (TGA)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<i>Product Chemistry</i>					
OCSPP 830.1550	Product Identity and Composition	49270901	Applied Silver, Inc.	Own	1
OCSPP 830.1600	Description of Materials Used to Produce the Product	49270901	Applied Silver, Inc.	Own	1
OCSPP 830.1620	Description of Production Process	49270902	Applied Silver, Inc.	Own	
OCSPP 830.1650	Description of Formulation Process	49270901	Applied Silver, Inc.	Own	1
OCSPP 830.1670	Discussion of Formation of Impurities	49270901	Applied Silver, Inc.	Own	1
OCSPP 830.1700	Preliminary Analysis	49270902	Applied Silver, Inc.	Own	
OCSPP 830.1750	Certified Limits	49270901	Applied Silver, Inc.	Own	1
OCSPP 830.1800	Enforcement Analytical Method	49270901	Applied Silver, Inc.	Own	1
OCSPP 830.6302	Color	RED	EPA Silver RED (1992)	PL	
OCSPP 830.6303	Physical State	RED	EPA Silver RED (1992)	PL	
OCSPP 830.6304	Odor	RED	EPA Silver RED (1992)	PL	
OCSPP 830.6313	Stability to normal and elevated temps, metals, ions	RED	EPA Silver RED (1992)	PL	
Signature <i>Sally Hayes</i>			Name and Title Sally Hayes, Agent		Date 12/20/2013

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¹ Not required for TGA



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DATA MATRIX

Date: December 20, 2013	EPA Reg No./File Symbol: 90335-X	Page 1 of 6
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	

Ingredient: Silver (TGA)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	1
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
Signature	Sally Hayes		Name and Title Sally Hayes, Agent	Date 12/20/2013	

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Date: December 20, 2013			EPA Reg No./File Symbol: 90335-X		Page 2 of 6
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545			Product SilvaClean™		
Ingredient: Silver (TGA)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OCSP 830.6314	Oxidation/Reduction: chemical incompatibility	49270901	Applied Silver, Inc.	Own	1
OCSP 830.6315	Flammability	49270901	Applied Silver, Inc.	Own	1
OCSP 830.6316	Explosibility	49270901	Applied Silver, Inc.	Own	1
OCSP 830.6317	Storage Stability	49270901	Applied Silver, Inc.	Own	1
OCSP 830.6319	Miscibility	49270901	Applied Silver, Inc.	Own	1
OCSP 830.6320	Corrosion Characteristics	49270901	Applied Silver, Inc.	Own	1
OCSP 830.6321	Dielectric Breakdown Voltage	49270901	Applied Silver, Inc.	Own	1
OCSP 830.7000	pH	RED	EPA Silver RED (1992)	PL	
OCSP 830.7050	UV/Visible light spectrum	RED	EPA Silver RED (1992)	PL	
OCSP 830.7100	Viscosity	49270901	Applied Silver, Inc.	Own	1
OCSP 830.7200	Melting Point/Melting Range	RED	EPA Silver RED (1992)	PL	
OCSP 830.7220	Boiling Point/Boiling Range	RED	EPA Silver RED (1992)	PL	
OCSP 830.7300	Density / Relative Density / Bulk Density	RED	EPA Silver RED (1992)	PL	
Signature <i>Sally Hayes</i>			Name and Title Sally Hayes, Agent		Date 12/20/2013



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Date: December 20, 2013		EPA Reg No./File Symbol: 90335-X		Page 2 of 6	
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545		Product SilvaClean™			
Ingredient: Silver (TGA)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	1
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			Applied Silver, Inc.	Own	1
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
Signature <i>Sally Hayes</i>		Name and Title Sally Hayes, Agent		Date 12/20/2013	



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Date: December 20, 2013			EPA Reg No./File Symbol: 90335-X		Page 3 of 6
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545			Product SilvaClean™		
Ingredient: Silver (TGA)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OCSP 830.7370	Dissociation Constant	49270901	Applied Silver, Inc.	Own	
OCSP 830.7520	Particle Size, Fiber Strength, Diameter Distribution	49270901	Applied Silver, Inc.	Own	
OCSP 830.7550	Partition Coefficient (n-Oct/H ₂ O) shake flask	RED	EPA Silver RED (1992)	PL	
OCSP 830.7560	Partition Coefficient (n-Oct/H ₂ O) generator column	RED	EPA Silver RED (1992)	PL	
OCSP 830.7570	Partition Coefficient (n-Oct/H ₂ O) estimation by liquid	RED	EPA Silver RED (1992)	PL	
OCSP 830.7840	Water Solubility: column elution/shake flask method	RED	EPA Silver RED (1992)	PL	
OCSP 830.7860	Water Solubility: generator column method	RED	EPA Silver RED (1992)	PL	
OCSP 830.7950	Vapor Pressure	RED	EPA Silver RED (1992)	PL	
Acute Toxicity Testing					
OCSP 870.1100	Acute Oral Toxicity	RED	EPA Silver RED (1992)	PL	
OCSP 870.1200	Acute Dermal Toxicity	RED	EPA Silver RED (1992)	PL	
OCSP 870.1300	Acute Inhalation Toxicity	RED	EPA Silver RED (1992)	PL	
OCSP 870.2400	Acute Eye Irritation	RED	EPA Silver RED (1992)	PL	
OCSP 870.2500	Acute Dermal Irritation	RED	EPA Silver RED (1992)	PL	
OCSP 870.2600	Skin Sensitization	RED	EPA Silver RED (1992)	PL	
Signature <i>Sally Hayes</i>			Name and Title Sally Hayes, Agent		Date 12/20/2013



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DATA MATRIX

Date: December 20, 2013		EPA Reg No /File Symbol: 90335-X		Page 3 of 6	
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545		Product SilvaClean™			
Ingredient: Silver (TGA)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Applied Silver, Inc.	Own	1
			Applied Silver, Inc.	Own	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			Signature <i>Sally Hayes</i>	Name and Title Sally Hayes, Agent	



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DATA MATRIX

Date: December 20, 2013		EPA Reg No./File Symbol: 90335-X		Page 4 of 6	
Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545		Product SilvaClean™			
Ingredient: Silver (TGA)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<i>Developmental Toxicity & Reproduction</i>					
OCSP 870.3700	Prenatal Developmental Toxicity-rat & rabbit	RED	EPA Silver RED (1992)	PL	
OCSP 870.3800	Reproduction and fertility effects	RED	EPA Silver RED (1992)	PL	
<i>Mutagenicity Testing</i>					
OCSP 870.5100	Bacterial Reverse Mutation Assay	RED	EPA Silver RED (1992)	PL	
OCSP 870.5300/5375	<i>In vitro</i> mammalian gene mutation	RED	EPA Silver RED (1992)	PL	
OCSP 870.5385/5395	<i>In vivo</i> cytogenetics	RED	EPA Silver RED (1992)	PL	
<i>Special Testing</i>					
OCSP 870.7800	Immunotoxicity	49270909	Applied Silver, Inc.	Own	
<i>Nontarget Organism Protection</i>					
OCSP 850.2100	Acute avian oral toxicity	43312901	Mason Chemical Company	Old	
OCSP 850.1010	Acute toxicity freshwater invertebrates	RED	EPA Silver RED (1992)	PL	
OCSP 850.1075	Freshwater fish toxicity	RED	EPA Silver RED (1992)	PL	
Signature 			Name and Title Sally Hayes, Agent		Date 12/20/2013



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Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	

Ingredient: Silver (TGA)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			Applied Silver, Inc.	Own	
			Mason Chemical Company	Old	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
Signature	Sally Hayes		Name and Title Sally Hayes, Agent		Date 12/20/2013



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Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545			Product SilvaClean™		
Ingredient: Silver (TGA)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<i>Aquatic Organisms Testing</i>					
OCSPP 850.1075/1400	Fish early-life stage	RED	EPA Silver RED (1992)	PL	
OCSPP 850.1300	Aquatic invertebrate life-cycle	RED	EPA Silver RED (1992)	PL	
<i>Nontarget Plant Protection</i>					
OCSPP 850.5400	Aquatic plant growth (algal) Tier II (dose response)	RED	EPA Silver RED (1992)	PL	
<i>Environmental Fate</i>					
OCSPP 835.2120	Hydrolysis	49270916	Applied Silver, Inc.	Own	
OCSPP 835.2240	Photodegradation in water	49270916	Applied Silver, Inc.	Own	
OCSPP 850.6800	Activated Sludge Respiration Inhibition Test	49270916	Applied Silver, Inc.	Own	
<i>Applicator Exposure</i>					
OCSPP 875.1100	Dermal exposure	49270909	Applied Silver, Inc.	Own	
OCSPP 875.1300	Inhalation exposure	49270909	Applied Silver, Inc.	Own	
OCSPP 875.1600	Data reporting and calculations	49270909	Applied Silver, Inc.	Own	
OCSPP 875.1700	Product use information	49270909	Applied Silver, Inc.	Own	
Signature <i>Sally Hayes</i>			Name and Title Sally Hayes, Agent		Date 12/20/2013



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Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545		Product SilvaClean™			
Ingredient: Silver (TGA1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			EPA Silver RED (1992)	PL	
			Applied Silver, Inc.	Own	
			Applied Silver, Inc.	Own	
			Applied Silver, Inc.	Own	
			Applied Silver, Inc.	Own	
Applied Silver, Inc.	Own				
Applied Silver, Inc.	Own				
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Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545			Product SilvaClean™		
Ingredient: Silver (TGA)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<i>Post Application Exposure</i>					
OCSPP 875.2700	Product Use Information	49270914	Applied Silver, Inc.	Own	
OCSPP 875.2800	Description of human activity	49270914	Applied Silver, Inc.	Own	
OCSPP 875.2900	Data reporting and calculations	49270914	Applied Silver, Inc.	Own	
Signature <i>Sally Hayes</i>			Name and Title Sally Hayes, Agent		Date 12/20/2013



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Applicant's/Registrant's Name & Address Applied Silver Inc. 26254 Eden Landing Road Hayward, CA 94545	Product SilvaClean™	

Ingredient: Silver (TGA)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Applied Silver, Inc.	Own	
			Applied Silver, Inc.	Own	
			Applied Silver, Inc.	Own	
Signature	Sally Hayes		Name and Title Sally Hayes, Agent	Date 12/20/2013	

SilvaClean™

SilvaClean™ is an antimicrobial silver treatment for commercial and industrial use on fibers or textiles. SilvaClean™ is effective in inhibiting the growth of bacteria in products to which it is applied.

Products containing SilvaClean™ may not make claims of antimicrobial activity other than protection of the article itself against odor-causing, staining, or deteriorating bacterial in the treated article. This product does not protect users against bacteria, viruses or other disease organisms.

SilvaClean™ is composed of:

Active Ingredient:

Silver*	22.5%
Other Ingredients	77.5%
Total	100.0%

* from silver nitrate.

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive

See back panel for first aid and additional precautionary statements.

Net Contents: _____

EPA Reg. No. 90355-x

EPA Est. No. xxx-xx-x

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

SilvaClean™ is applied to or incorporated into industrial products listed below. For non-food contact uses only.

FOR APPLICATION IN COMMERCIAL AND INSTITUTIONAL SETTINGS

Textiles made of: cotton and cotton/polyester blend. Example items include: pillow covers; sheets; blankets; bedspreads; apparel; uniforms; scrubs; lab coats; quilts; curtains; draperies; upholstery; towels; and shower curtains.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its label.

This product is registered as a microbiostatic agent for material preservation; neither this product nor the articles treated with this product may state or imply any public health claims. Articles or substances treated with this product will be exempt from FIFRA regulation pursuant to 40 CFR 152.25(a) if the intended use for incorporating this material into a treated article or substance is for the protection of the article or substance itself.

SilvaClean™ is an antimicrobial silver application that provides 0.00013% to 0.0014% (1.3 ppm – 14 ppm) silver on fibers or textiles. The treatment level of SilvaClean™ for a product will depend on the specific needs of the manufacturer, the textile being treated, and the level and type of performance desired.

Solution Preparation and Treatment: SilvaClean™ is a concentrate that must be diluted with distilled or deionized water before use. Treat textile by soaking in dilute aqueous solution and agitating for at least 2 minutes. Contact Applied Silver, Inc., for dilution and treatment instructions specific to your desired performance.

Textile must be clean prior to the application of product. Retreat textile after each laundering.

STORAGE and DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in a safe manner only in areas inaccessible to small children. Store in original container in dark location. Keep container tightly closed when not in use.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, intermediate mixtures, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA regional office for guidance.

Container Handling: Non-refillable container – do not reuse or refill this container. Return container to Applied Silver, Inc.

PRECAUTIONARY STATEMENTS AND FIRST AID

DANGER

Corrosive

Causes irreversible eye damage and skin burns. Harmful if absorbed through skin, swallowed or inhaled. Do not get in eyes, skin or on clothing. Avoid breathing vapor or spray mist. Wear goggles, face shield and chemical resistant clothing (waterproof apron, waterproof gloves covering hands, wrists, and lower forearms). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

First Aid

If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
If swallowed:	Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or when going for treatment.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters. This product is toxic to fish and aquatic invertebrates.

